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# Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review



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Title Page

**Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review**

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**Abstract**

Objectives: To identify features of programmes and approaches to make healthcare delivery in secondary healthcare settings more dementia friendly, providing a context-relevant understanding of how interventions achieve outcomes for people living with dementia.

Design: A realist review conducted in three phases (1) stakeholder interviews and scoping of the literature to develop an initial programme theory for providing effective dementia care; (2) structured retrieval and extraction of evidence; (3) analysis and synthesis to test and refine the programme theory.

Data sources: PubMed, CINAHL, Cochrane Library, NHS Evidence, Scopus, grey literature.

Eligibility criteria: Studies reporting interventions and approaches to make hospital environments more dementia friendly. Studies not reporting patient outcomes or contributing to the refinement of the programme theory were excluded.

Results: Phase 1 combined findings from 15 stakeholder interviews and 22 publications to develop candidate programme theories. Phases 2 and 3 identified and synthesised evidence from 28 publications. Prominent context-mechanism-outcome configurations were identified to explain what supported dementia-friendly health care in acute settings. Staff capacity to understand the behaviours of people living with dementia as communication of an unmet need, combined with a recognition and valuing of their role in their care prompted changes to care practices. Endorsement from senior management gave staff confidence and permission to adapt working practices to provide good dementia care. Key contextual factors were the availability of staff and an alignment of ward priorities to value person-centred care approaches. Preoccupation with risk generated responses that were likely to restrict a patient's choices and increase their distress.

Conclusions: This review suggests strategies such as dementia awareness training alone will not improve dementia care or outcomes for patients with dementia. Instead, how staff are supported to implement learning and resources by senior team members with dementia expertise is a key component for improving care practices and patient outcomes.

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**Strengths and limitations of this study**

- Applying realist methods enabled a theory-driven explanation of how dementia friendly health care can be supported in hospital settings
- The process of the review facilitated the development of a new programme theory, which can be used to inform future initiatives that support people with dementia in hospital environments
- The involvement of stakeholders from the outset ensured the plausibility and relevance of the findings for hospital environments
- The extent of evidence to support some elements of the programme theory was limited, especially where interventions lacked specificity about process and patient outcomes.

**Key words**

People living with dementia, hospitals, dementia, realist review, dementia friendly

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## INTRODUCTION

There is increasing recognition that hospital staff and services need to understand the complexity of caring for and treating people living with dementia [1]. At any one time, 25% of hospital beds are used by people living with dementia, rising to a higher proportion on some wards [2]. Co-morbidities are common and many people are admitted to hospital for reasons not directly related to their dementia [3-5]. Healthcare outcomes for people living with dementia are variable across the country and are inequitable when compared to outcomes for people without cognitive impairments [5]. Adverse incidents occurring during admissions, such as falls, poor nutrition and hydration, infections, and the onset of delirium, contribute to longer stays and reduced functional abilities which may result in admission to a care home [6-8].

A number of factors may impact on the disparity of health outcomes for people living with dementia including: a lack of focus and leadership for dementia in hospitals [5]; healthcare staff who have inadequate knowledge and training in dementia and dementia care [9, 10]; difficulties faced by healthcare professionals when assessing the risk and benefits of treatment options [11]; widespread use of care practices which are detrimental to people living with dementia, such as the use of antipsychotics for behavioural management [12]; stigma and discrimination towards people living with dementia [13, 14]; and confusing, unsafe environments [15]. The National Dementia Strategy [16] aimed to improve the quality of care for people living with dementia in general hospitals through leadership that addresses quality improvements in dementia care, defined care pathways, and the use of liaison mental health teams. It also highlighted the importance of education and training to break down the stigma associated with dementia and to develop dementia awareness within the healthcare workforce. To address these ambitions, interventions have been designed and implemented with the aim of creating dementia friendly health care in hospitals [17, 18].

### Dementia Friendly

The concept of dementia friendly developed from initiatives to promote age-friendly communities [19]. It was first used to describe physical and social environments that promoted inclusion, acceptance and accessibility for people living with dementia [20, 21] and includes initiatives supporting the independence and safety of people living with dementia [22]. In the UK this includes the Dementia Friends initiative [23] and the Dementia Engagement and Empowerment Project (DEEP) [24].

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At the patient level, dementia friendly healthcare is the practice and organisation of care that is aware of the impact dementia has on a person's ability to engage with services and manage their health. It promotes the inclusion of people living with dementia and their carer in treatments, care decisions and discussions, with the aim of improving outcomes for the patient and carer [16, 17, 25-27].

Interventions to promote dementia friendly healthcare environments have been diverse in terms of their design and application in practice [27-29]. This review of the evidence acknowledges that the effectiveness of programmes to address the known problems of being a patient with dementia is contingent on multiple factors such as staff knowledge and skills in dementia care, the care environment, and the competing demands on staff time and attention. The overall aim of this review is to develop a theory-based explanatory account of how hospital settings have applied dementia friendly environments, and their impact on people with dementia and their informal carers. This includes the identification of key contextual factors that support dementia friendly healthcare environments, and the development of evidence-based explanations to understand what it is about dementia friendly healthcare interventions that works for people living with dementia and their carers, in what circumstances and why.

## METHOD

Realist review methods were used to develop a theoretical understanding of what supports effective dementia care in hospital settings. There were three overlapping, iterative phases: 1) defining the scope of the review informed from key literature and stakeholder interviews; 2) structured searches, screening, and data extraction; 3) analysis and synthesis leading to refinement of the programme theory. A fuller account of the review protocol is available in Handley, et al. [30].

The phases did not follow a linear format, but informed and refined understanding throughout the review, leading to new interpretations and testing of evidence. Sources were identified and revisited, new evidence was incorporated, and inclusion criteria reconsidered as new theoretical understanding developed. The RAMESES publication standards informed the preparation of this report [31].

### Phases of the Realist Review

*Phase one: Defining the scope of the review: concept mining and theory development*

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Evidence from interviews with stakeholders and a scoping of the literature was used to identify the range of dementia friendly interventions in health care settings both in the UK and internationally, determine possible theoretical assumptions about how and why interventions were thought to work (or not), and clarify what were thought to be the significant mechanisms for change. Stakeholders, people who had experience in designing, implementing, and using dementia friendly interventions, were identified from knowledge within the team, internet searches, and dementia specific conference abstracts. Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

Data were coded using framework analysis [32] with emerging themes and competing accounts discussed and debated amongst the authors (MH, FB, CG) and with Alzheimer's Society research network monitors (RP, JW, PM) who were volunteer representatives with experience of caring for family members living with dementia. Credible evidence informed hypotheses in the form of 'If… then statements' were used to set out the conditions thought to be necessary for outcomes to be achieved. These informed discussions amongst the authors and the development of a conceptual framework [33]. Three overlapping theoretical propositions were generated to explain what supports the implementation and uptake of interventions that promote dementia friendly health care within a ward based environment.

*Phase two: Retrieval and review*

*Searching for relevant studies*

Informed by the theoretical propositions derived from the work in phase one, search terms were revised. The inclusion/exclusion criteria were refined to focus on studies which reported patient outcomes and provided information about the characteristics and role of change agents (staff who supported the implementation and uptake of interventions).

Searches were limited to 2000 – 2015 to reflect the impact of the work of Kitwood and Bredin [34] on dementia care practices that recognise the importance of person-centred care and the promotion of personhood. In addition to the electronic database searches (box 1), we undertook extensive lateral searching, including forward and backward citations, and contact with experts. Additional searches for studies relating to the role of change agents, the assessment and treatment of pain, and ways to manage behaviours that challenge were used to refine theory development until theoretical saturation was achieved [35, 36] (box 1).

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Box 1: Phase two search terms and search strategy

Searches initially run September 2015, search alerts scanned to February 2016

Language restricted to English

Date restricted 2000 – 2015

Search terms:

(dementia AND (friendly OR appropriate OR awareness OR champion OR liaison OR ward OR environment OR education OR training OR nurse specialist OR lead* OR person centred care) AND (hospital OR acute care OR secondary care))

Additional search terms developed from findings in phase one:

dementia AND (change agent OR champion OR knowledge transfer OR knowledge translation OR opinion leader)

(dementia AND (pain) AND (hospital OR acute care OR secondary care))

(dementia AND (behaviour* OR BPSD) AND (hospital OR acute care OR secondary care))

Databases:

Cochrane Library (incl. CENTRAL, CDSR, DARE, HTA) (244), CINAHL (610), PubMed (4253), NHS Evidence (819) and Scopus (410)

*Study screening and data extraction*

Search results were downloaded into EndNote bibliographic software and duplicates deleted. One author (MH) screened titles and abstracts identified by the electronic search and applied the selection criteria to potentially relevant papers. Full texts of potentially relevant manuscripts were screened for relevance (whether the study has contributed to specific propositions relevant to the theory building and testing) and rigour (whether they of sufficient quality to provide credible evidence to help refine specific components of the proposition) [31, 33]. Appraisal of the contributions and reliability of evidence from papers continued throughout the synthesis through discussion with the other authors.

Data were extracted by one author (MH) using a bespoke data extraction form organised to establish contributions and challenges to the theories and strengths and weaknesses of the studies. Study characteristics such as design, setting, participants and sample size were

also recorded [31]. The inclusion of coded data and its contribution to theory development were debated with FB and CG, and challenges to interpretations were discussed to test their credibility. Information about the role and work of the change agent, the resources provided by the interventions, the contextual features of the settings (e.g. workforce, knowledge of dementia), explicit and implicit theories for how interventions were anticipated to work, and patient and carer outcomes were extracted. Evidence from the studies were first mapped to capture the complete range of possibilities of how different approaches and interventions triggered different responses from patients, family, and staff. After discussion amongst the authors, data were organised into tables to reflect the theoretical propositions they addressed (supplementary file 1) and to assist comparison of data across studies.

*Phase 3: Analysis and Synthesis*

Data synthesis was led by MH, with emerging findings discussed with the team (CG and FB), and the research network monitors (RP, JW, PM). Deliberations assisted the refinement of propositions, ensuring that emerging theories were plausible and clear. Discussions of papers included: the key characteristics of members of staff who support the implementation and uptake of interventions, resources, and new ways of working with people living with dementia (change agents); resources from interventions and how they were thought to influence staff reasoning; facilitating and constraining contexts; and possible undesired outcomes (such as stigmatising practises and broad application of strategies at the expense of individual needs). The focus was on understanding how patient outcomes were achieved through the actions of staff and what had supported staff to behave in particular ways. Recurring patterns in context and outcome (demi-regularities) detectible across studies were explained by explicit or implicit mechanisms. This led to the development of context-mechanism-outcome configurations designed to explain what it is about an intervention that works, for whom, and in what circumstances. The configurations were used to test components of the initial theoretical propositions against the evidence.

## FINDINGS

### Phase 1

Evidence from 15 stakeholders was combined with literature on interventions aimed at improving health care for people living with dementia (22 papers) to generate three initial propositions for developing dementia friendly hospital environments. Stakeholders were drawn from a range of settings (academia, health care, commissioning, social work, the community) and backgrounds (nursing, education, physiotherapy, research, person living with dementia). Interventions described in the literature can be seen in table 1.

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Table 1: Papers included in Phase 1

| Intervention | Papers |
|---|---|
| Schemes to identify people with dementia admitted to the ward: e.g. a butterfly symbol above patient's bed to help identify people who have dementia linked to a training programme and the collection of biographical history from the family carer | [37] |
| Dementia Champion - Healthcare staff (mainly nursing staff) are trained to champion dementia care issues, providing support to peers | [27, 38-42] |
| Dementia Specialist Nurse - Senior Nurse working across the hospital as an expert in dementia to advise staff on treatment and care practices, and liaise community services. | [43, 44] |
| Staff training and education - Training in dementia awareness and dementia care. | [9, 10, 28] |
| Liaison psychiatry / mental health teams - Specialist teams working across the hospital to advise staff on treatment and care and the treatment of delirium. | [45, 46] |
| Environmental adaptions - Changes to clinical areas including signage, new furniture, and improved flooring and lighting. | [15, 47] |
| Specialist Units for people living with dementia– include physical adaptions and specialist staff to treat the medical and psychological needs of people living with dementia | [48-52] |
| Use of Person Centred Care - model of care that priorities the needs of the person. | [53] |

A key contextual factor to emerge from Phase 1 related to the role of change agents, although there were competing accounts of how a change agent might work and the responses they might trigger in staff. There appeared to be three distinct roles for change agents' activities that could lead to improved outcomes, these were;

- To support staff awareness and learning,
- To possess the authority to institute and sustain changes,
- To be a resource for staff as a clinical expert.

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Change agent characteristics (e.g. supportive peer facilitator, organisational authority, clinical expertise) were considered to differently influence how staff engaged with interventions, and this, in turn, would impact on patient outcomes (table 2).

Table 2: Initial theoretical propositions developed from phase 1

| Dementia friendly interventions in hospitals improve outcomes for people living with dementia and their carers if… | Evidence from stakeholders and preliminary scoping and supporting references |
|---|---|
| … a change agent supports staff to reframe their understanding of dementia and respond appropriately to people living with dementia through learning and resources which address patient needs in an individual way. **Then** staff will have increased awareness of dementia and the impact dementia has on a person, and build confidence in their ability to recognise and address distress. | Emphasis on training and education that improve staff confidence in working with people living with dementia. Breaking down negative assumptions and supporting staff to see the person rather than the diagnosis. Use of resources to get to know the person.<br><br>References: [9, 10, 28, 37-40, 42, 53-55]<br><br>Stakeholders (SK01, SK02, SK03, SK04, SK05, SK06, SK07, SK09, SK10, SK11, SK12, SK13, SK14)<br>Example quote: "we're starting to do some training with our staff as well just to try and help everyone to know how to approach and how to feel empathy towards these patients who have dementia." (SK12) |
| … a change agent with organisational and clinical authority communicates the priorities for dementia care and addresses staff concerns around managing risk and workplace disruption in person-centred ways. Staff are supported by training and resources that improve the involvement in decision-making and safety of people living with dementia, **then** staff will understand they have the permission and | Strategic planning, prioritising good dementia care, providing resources that support staff to work in new ways, changes to systems and processes<br><br>References: [15, 40, 47-53]<br><br>Stakeholders (SK05, SK06, SK07, SK08, SK10, SK11, SK14, SK15) |

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| encouragement to adapt practices in ways that are beneficial for people living with dementia. | Example quote: "…however good people's ideas are, if they don't have some kind of sign-off at a fairly senior level then they're not really going to have it 'cos they'll never be a priority and because there are so many targets to be met in general, unless there's some kind of strategy or policy in writing I don't think it can change much really." (SK08) |
| … a change agent with clinical expertise in dementia and dementia care supports staff with assessments and care planning **then** staff will identify and resolve the care needs of people living with dementia. | Assessments of cognition, mental health, and psychosocial needs. Role modelling good dementia care. Supporting staff to perform care in a person-centred way, direct care planning and address complex issues such as decisions of best interest, access to mental and social care information.<br><br>References: [43, 45, 46, 48-50, 56]<br><br>Stakeholders (SK04, SK09, SK11, SK14, SK15)<br>Example quote: "we had mental health nurses came to work with us and they had a really important part in role-modelling how it looked, how to approach things." (SK14) |

**Phase 2**

Evidence from 28 papers led to the development of six context-mechanism-outcome configurations (CMOs) that tested the components of the three theoretical propositions developed in phase one (an overview of the selection process can be seen in Figure 1). These configurations are interconnected, representing key elements from the theories and how they relate to other factors (table 3). The CMOs and supporting evidence are discussed below.

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Table 3: Context-mechanism-outcome configurations and supporting evidence

| Brief title | Full Context-mechanism-outcome configuration | References |
|---|---|---|
| Supporting staff to reframe their understanding and how they respond to behaviours that challenge | Staff who are supported to understand and interpret behaviours that challenge as communication of an unmet need through training, resources and support from experts in dementia care (context), will prioritise addressing the cause of the behaviour to meet the person's individual needs (mechanism), improving health outcomes and patient experience (outcome). | [10, 15, 37, 38, 40, 43, 48, 50-53, 57-68] |
| The role of experiential, learning creating empathy and how it encourages reflection | Training which promotes experiential learning, and empathy towards people living with dementia (context) will encourage reflection on working practices and instil a sense of responsibility to work well with people living with dementia (mechanism), leading to improved patient outcomes (outcome). | [10, 37, 38, 57, 60-62] |
| Clinical experts who support staff and have the authority to endorse priorities for care | Staff who are supported by experts to develop skills in dementia care, and are aware the priorities and standards for dementia care are endorsed by the organisation (context), will be understand they have permission (mechanism) to work in ways which improve patient safety and experience (outcome). | [38, 40, 43, 46, 48, 51-53, 57, 59-62, 67-69] |
| Staff who have flexibility to provide care at an appropriate time | Staff with flexibility in their role and working environment (context), will use their professional judgement to provide care and treatment to a person in a timely manner (mechanism), will support patients in a person-centred way that is responsive to their needs (outcome). | [48, 53, 59, 60, 67] |

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|---|---|---|
| Staff with responsibility to focus on psychosocial needs | Staff with a role to address psychological, emotional and social issues (context) are responsible (mechanism) for activities and therapies with people living with dementia that support their interests and abilities, helping to maintain functional and cognitive abilities, (outcome), and provide other healthcare staff with time to prioritise physical and medical needs (outcome). | [10, 48, 49, 52, 53, 60, 62, 63, 66, 68, 70] |
| Building staff confidence to provide person-centred risk management | Staff who understand the procedures and expectations for care that address risk in a person-centred way (context), and are confident that they are supported by organisation (mechanism) will improve patient safety and address risk proportionately, reducing distress and the occurrence of adverse incidents (outcome). | [10, 15, 37, 48, 49, 51, 52, 62, 64-66, 68, 69] |

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*CMO 1. Supporting staff to reframe their understanding and how they respond to behaviours that challenge*

Studies frequently reported that where staff understood behaviour that challenged as communication of an unmet need, they were more likely to investigate the underlying cause rather than attempting to control and restrict the behaviour [15, 38, 40, 51, 58, 64, 68]. By addressing the unmet need, staff reduced patient distress [53, 57, 60, 61, 63, 68, 71] and maintained independence, for example by supporting mobility and toileting needs [37, 52, 62, 67]. Inappropriate and negative staff responses arose from lack of understanding and misinterpretation of behaviours that challenge, for example, interpreting the patient as being deliberately difficult [50, 66].

Strategies employed to reframe staff understanding of behaviours included: training in dementia [10, 15, 53, 57, 60]; the use of biographical tools, completed in partnership with informal carers, [38, 51, 65, 68, 72]; assessments of cognition, pain, and psychological needs [48, 52, 58, 73]; and access to experts in dementia care [38, 40, 43, 48, 52, 68]. These resources reportedly supported the development of individualised care plans [43, 65] and personalised strategies for reducing distress [37, 68]. Training to recognise behaviours as the expression of an unmet need [57, 59], and knowledge of a patient gained through continuity in their care [53, 59, 60] helped staff recognise they needed to adapt their work to suit the individual. However, personalisation of practices appeared to occur in pockets of activity rather than as an ethos of care provision. Even when staff understood and were supported to work well with people living with dementia with behaviours that challenged, their ability and willingness to address psychological needs was limited. Conflicting work demands, staff fatigue, long shifts, and difficulty in identifying and resolving patient issues resulted in staff responding to behaviours by ignoring and disengaging from the patient [48, 63].

*CMO 2. The role of experiential learning, creating empathy and how it encourages reflection*

Staff training that improved awareness of the impact of dementia and which addressed negative concepts was found to be a prerequisite for supporting good dementia care. Training was shown to have a positive impact on knowledge and confidence for working with people living with dementia, however how this changed staff behaviours was largely anecdotal [10, 37, 38, 57].

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Training strategies which employed experiential learning techniques and cultivated empathy in staff for people living with dementia prompted reflection on current practices. Evidence suggested these training sessions produced 'lightbulb moments' for staff where they gained a sudden realisation of the problems faced by people living with dementia [38, 57, 62]. This appreciation for the importance to adapt care practices prompted staff to work in ways that would better support the patient, and improved staff satisfaction with their work [37, 70]. Additionally, one study reported how staff associated the portrayals of people living with dementia in training materials to their own relatives. This encouraged staff to see people living with dementia as individuals and motivated them to take responsibility to put their learning into practice [57].

The use of reflection and examples of good care practices in recognisable situations gave staff a framework for working well with people living with dementia and demonstrated the benefit to their own work [57, 62]. However, these practices were often referred to by staff as 'going the extra mile' or being additional to their workload rather than being an expectation of their role. Staff needed to be confident additional time spent with patients would not be viewed negatively by colleagues or impact on the requirements to manage the ward effectively.

*CMO 3. Clinical experts who support staff and have the authority to endorse priorities for care*

Change agents influenced staff working practices through clinical expertise and organisational authority [38, 40, 43, 46, 48, 52, 60, 61, 68]. Experts in dementia care supported staff in the use of assessment tools and person-centred care planning [46, 52], role modelled appropriate behaviour and communication for working with people living with dementia [38, 48], and provided professional advice for complex situations, such as decisions around best interests [40, 43]. However, there was limited evidence that new practices were adopted by staff and embedded into everyday practice directly through their contact with dementia experts. Instead, it appeared that the experts maintained responsibility for dementia care, either personally or by providing direction. The use of experts alone could potentially concentrate responsibility for dementia care in a small staff group rather than create a culture where all staff are responsible. Evidence from one paper [48] suggested that even when ward staff as a whole were better able to work with people living with dementia, they would defer issues unrelated to physical or medical health care to dementia experts.

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Clinical experts with a level of organisational authority endorsed changes to care practises by communicating values and standards for care at ward level [52, 53, 57, 60, 69] and across the organisation [51, 57, 61]. They addressed staff apprehensions to adaptions to care practices that previously prioritised medical and physical needs, ward routines, task focused ways of working, and organisational expectations for the completion of documentation and risk reduction [66]. Our review found when change agents in authority communicated new expectations for standards of care and changes to procedures, they validated the priorities for care permitting staff to adapt practices accordingly [51, 52, 57, 69]. However, the impact of changes to staffs' work needed to be recognised and supported [48, 51, 52, 60, 67-69]. For example, studies reported staff had reduced capacity to work with previous levels of patient allocation [51, 60, 67], and changes to risk management strategies, such as encouraging mobility in a frail patient population at risk of falls, required staff training [52, 69].

*CMO 4. Staff who have flexibility to individualise care*

The ability of staff to organise their work around the needs of people living with dementia rather than being restricted to the ward routine was linked to the provision of person-centred care [48, 53, 59, 60, 63, 67]. Where staff could incorporate getting to know the person, or recognise and respond directly to expressions of distress and unmet needs, patient wellbeing reportedly improved, with both observed and anecdotal evidence of improved mood [53, 59, 60, 63].

Flexibility in working practices could also improve functional outcomes for people living with dementia. Rösler, et al. [67] attributed gains in mobility after hip surgery to therapy staff using their professional judgement to recognise optimal times that a person living with dementia would engage with a psychotherapy session, rather than risk the session being rejected. Additional factors that supported therapy staff to work flexibly included training in dementia care, reduced patient lists, and treatment rooms located on the ward [74].

*CMO 5. Staff with responsibility to focus on psychosocial needs*

Time constraints and staffing resources limited staff capacity to provide good dementia care. This was often addressed by employing staff with a specific role prioritising psychological, emotional and social needs through the use of cognitive and psychosocial assessments, therapeutic activities, supervising mealtimes, and managing risk [10, 48, 50, 52, 60, 63, 66]. The use of these staff and the activities they provided improved patient experience [60],

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assisted orientation to time and place [63], reduced distress [48, 60, 63], and reduced the onset of behaviours that challenged staff [48]. Studies reported how activities were sometimes deliberately scheduled to cover known times of high need within the patient population, such as during the afternoon when sun-downing might occur [52] or when staffing levels were stretched, such as during mealtimes. For example, activities co-ordinators offered social dining opportunities where they could support conversations and prompt patients to eat [48, 60, 63, 68]. Although studies reported improved nutritional intake this was not formally evaluated.

Patients with more severe physical illness or cognitive impairment may not be able to participate in activities [48, 50] although it is possible they may have benefited indirectly as healthcare staff had more time to address their physical and medical needs. While this was referred to in two of the interviews, this was not explored in any of the papers.

Ward-wide staffing levels and skill mix impacted on staff ability to prioritise emotional, psychological and social needs [48, 60]. At times of staff shortages, ward management prioritised safety and managing risk over other non-medical needs [48, 60]. Risk management techniques, such as the use of 'specials' could be applied in a way that also addressed psychosocial needs. Two studies [48, 60] described how staff allocated to monitor patients at risk of falls engaged the patients in games, activities, and conversations. However, this was not always the case as staff assigned as specials were often junior team members, had not received training in dementia care, and were unclear of the purpose of the role beyond monitoring the patient. This resulted in a lack of interaction with the patient and increased patient distress [66].

*CMO 6 Building staff confidence to provide person-centred risk management*

We found evidence that addressing risk in a way that supported a person's abilities, choices and independence improved mobility [52, 62], reduced adverse incidents [68], and improved patient and carer satisfaction [48, 51, 65]. Training, for example, on new skills and procedures for managing risk from change agents with clinical expertise and organisational authority, ensured staff understood the benefits to patients and had confidence to implement approved working practices [52, 65, 69]. Structural factors influenced the way risk was addressed. For example wards with locked door access meant patients could be monitored from a distance without restricting their movement around the ward [48, 51, 52, 64]; potentially

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leading to a reduction in behaviours that challenge as 'wandering' behaviours were no longer considered problematic.

In open wards, alternative methods were developed to easily identify patients considered at risk of leaving the ward, such as the use of wrist bands and different coloured hospital clothing, allowing staff to monitor them from a distance and intervene as necessary [10, 57, 62]. Identification methods were supported by staff training in the appropriate way to encourage a patient to return to their ward [10, 62].

**Refined theory**

Evidence from these context-mechanism-outcome configurations was used to test the original theoretical propositions and led to a theory of what needs to be in place to promote best practice in dementia care in hospital settings. We identified a number of important components for the provision of dementia friendly health care. Staff required an awareness of dementia and the issues for dementia care which emphasises that a person's needs are expressed through behaviour. Psychosocial and physical needs of people living with dementia should be identified and addressed equally. Staff must have clarity in their role and responsibilities for the priorities for caring for people living with dementia. A level of organisational authority endorsing changes to care practice is important for staff to understand they have permission and encouragement to provide good dementia care. Improved outcomes for people living with dementia are dependent upon their individual care needs being understood and met in order to reduce distress that might otherwise complicate treatment of their acute needs.

**DISCUSSION**

Our review demonstrates how consideration of different contextual components in hospitals, hospital staff, and patients was fundamental to an intervention leading to improved healthcare outcomes for people living with dementia. Developing an understanding in staff of the difficulties dementia presents for people with the condition helped them to recognise the need to approach care differently. Previous reviews of dementia care in hospital settings have identified training as an important strategy to improve staff knowledge of dementia and confidence to work well with people living with dementia, but have provided limited evidence for how this effects patient outcomes [29, 75, 76]. Findings from this review would suggest that training as a single strategy is not enough to influence staff to adapt the care they

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provide for people living with dementia. The culture of care within an organisation needs to support staff to provide good care for people living with dementia. This means organisations need to recognise the impact this has on staff workload and roles and the changes that are necessary to ensure care provision has more flexibility. Staff needed to have a clear understanding of the expectation for care standards, and be confident that these changes are accepted by colleagues and senior staff if they are to improve the way care is provided for people living with dementia. Managerial endorsement for staff to work flexibly within their role, utilising practices and resources that enable them get to know the person, will help staff to recognise and address signs of distress and implement best practice in dementia care.

Turner, et al. [75] suggests that to achieve the type of culture where person-centred care is valued, training in dementia should be aimed at a managerial level. Findings from this review would support their opinion; included studies where change agents in senior positions understood dementia and the associated impact on patient experience and care of the patient were reportedly able to influence the culture of care [51-53, 57, 61, 68, 70]. They communicated their vision for good dementia care, addressed the organisation of processes within and between departments, provided resources that supported staffs' work, and considered the impact of changes to roles and responsibilities. However, even with this endorsement, there were still times, such as concerns for managing risk and resource shortages, where staff responsibilities were reorganised to prioritise physical over psychological wellbeing.

Limited time and resources, and a preoccupation with managing risk are commonly cited factors that impact on the ability of staff and organisations to sustain dementia friendly hospital environments [29, 66, 75, 77, 78]. Employing staff who have a responsibility for the psychosocial needs of the patient can potentially improve patient experience of care while also making time available for nursing and medical staff to focus on physical and medical care needs of the patient. However, it is essential that contextual factors, such as staff awareness in dementia and dementia care, and staff clarification of their role and responsibilities are addressed before staffing resources are implemented into the setting. Moyle, et al. [66] demonstrated how the use of ‘specials’ without training in dementia care, a clear understanding of their role, and a prioritisation of risk management over addressing psychosocial needs resulted in poor outcomes for patients, such as increased agitation and reduced autonomy. A review on special observation [79] underlined the importance of clarity in the purpose of the role and adequately trained staff to optimise the role’s therapeutic potential. Where responsibilities for care are assigned solely by the patient’s symptoms this

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can lead to a narrow reactive approach to dementia care. Staff will still a need to work as a team, rather than creating new tasks to focus on.

There were a number of limitations to this study. There was a lack of available literature in the area. A large proportion of the identified literature was descriptive rather than an evaluation of interventions and approaches. Included papers were limited in their descriptions of the setting and component parts of interventions. This led to the identification of partial context-mechanism-outcome configurations. Most studies included in the review only reported limited information around patient characteristics. This meant the review was unable to establish how the characteristics of people living with dementia interacted with the components of the interventions to influence their outcomes. Much of the evidence for patient outcomes was anecdotal and focused on the processes of care. While this helps to identify the assumptions of the programme theories being tested, it was limited in the evidence provided for what the interventions actually achieved.

## CONCLUSION

The programme theory that has emerged from this review has the potential to improve how interventions to support dementia friendly care in hospitals are designed and evaluated. The review highlights what needs to be in place to maximise the impact of training and the key characteristics for staff acting as change agents to influence colleagues to practice good dementia care. Specifically, the elements of interventions need to be relevant to provide ward staff with the awareness, authority, and resources to provide personalised care with support from staff with the relevant expertise. Educational interventions should focus on how staff can identify with the experience of being a patient living with dementia, combined with opportunities for staff to share their experiences of addressing challenges linked with the impact of dementia related behaviours on ward routines and priorities. This review provides a timely contribution and challenges the assumption that dementia awareness initiatives in acute care settings alone are sufficient to improve patient care.

## CONTRIBUTORS

MH the design and prepared the review as part of her PhD (University of Hertfordshire, Hertfordshire, UK) and led manuscript preparation. FB and CG wrote the original funding application, supervised the review development, and critically reviewed manuscript drafts. All authors contributed to the debate and interpretation of data, read, and approved the final manuscript.

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## AVAILABILITY OF DATA AND MATERIAL

All evidence cited in this review is available in the public domain. Data from the stakeholder interviews are not available to protect individuals' anonymity.


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## DISCLAIMER

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the paper.

## COMPETING INTERESTS

The authors declare that they have no competing interests.

## ETHICS APPROVAL

Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

## CONSENT FOR PUBLICATION

Participants in stakeholder interviews consented to participation and the use of anonymised interview excerpts.


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For peer review only

## REFERENCES


1. Alzheimer's Society. Fix Dementia Care: Hospitals. London: Alzheimer's Society, 2016.
2. Alzheimer's Society. Counting the cost: Caring for people with dementia on hospital wards: Alzheimer's Society London, 2009.
3. Poblador-Plou BC-L, Amaia; Marta-Moreno, Javier; Hancco-Saavedra, Jorge; Sicras-Mainar, Antoni; Soljak, Michael; Prados-Torres, Alexandra. Comorbidity of dementia: a cross-sectional study of primary care older patients. *BMC psychiatry* 2014;**14**(1):84
4. Bunn FB, Ann-Marie; Goodman, Claire; Rait, Greta; Norton, Sam; Robinson, Louise; Schoeman, Johan; Brayne, Carol. Comorbidity and dementia: a scoping review of the literature. *BMC medicine* 2014;**12**(1):192
5. Royal College of Psychiatrists. Report of the national audit of dementia care in general hospitals 2011: Healthcare Improvement Quality Partnership, 2013.
6. Bunn F, Dickinson A, Simpson C, et al. Preventing falls among older people with mental health problems: a systematic review. *BMC nursing* 2014;**13**(1):4
7. Orsitto G, Fulvio F, Tria D, Turi V, Venezia A, Manca C. Nutritional status in hospitalized elderly patients with mild cognitive impairment. *Clinical Nutrition* 2009;**28**(1):100-02
8. Bail K, Goss J, Draper B, Berry H, Karmel R, Gibson D. The cost of hospital-acquired complications for older people with and without dementia; a retrospective cohort study. *BMC health services research* 2015;**15**(1):91
9. Elvish RB, Simon; Cawley, Rosanne; Harney, Kathryn; Graham, Pat; Pilling, Mark; Gregory, Julie; Roach, Pamela; Fossey, Jane; Keady, John. 'Getting to Know Me': the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & mental health* 2014;**18**(4):481-88
10. Galvin JEK, Barbara; Al-Hammadi, Noor; Germino, Jessica; Murphy-White, Maggie; McGillick, Janis. "Dementia-friendly hospitals: care not crisis" An educational program designed to improve the care of the hospitalized patient with dementia. *Alzheimer disease and associated disorders* 2010;**24**(4):372
11. Bunn F, Goodman C, Brayne C, et al. Comorbidity and dementia: improving healthcare for people with dementia. www. nets.nihr. ac. uk/projects/hsdr/11101707. NIHR, HS & DR, 2012.
12. White N, Leurent B, Lord K, Scott S, Jones L, Sampson EL. The management of behavioural and psychological symptoms of dementia in the acute general medical hospital: a longitudinal cohort study. *International Journal of Geriatric Psychiatry* 2016
13. Benbow SMJ, David. Dementia: stigma and its effects. *Neurodegenerative Disease Management* 2012;**2**(2):165-72
14. Swaffer K. Dementia: Stigma, Language, and Dementia-friendly. *Dementia* 2014;**13**(6):709-16 doi: 10.1177/1471301214548143published Online First: Epub Date]|.
15. Waller S, Masterson A. Designing dementia-friendly hospital environments. *Future Hospital Journal* 2015;**2**(1):63-68
16. Department of Health. Living Well with Dementia: a national dementia strategy. In: Health Do, ed. London, 2009.
17. Department of Health. Prime Minister's challenge on dementia 2020. In: Health Do, ed. London, 2015.
18. Health Education England. Dementia: Improving dementia care through effective basic training and continuous professional and vocational development. Secondary Dementia: Improving dementia care through effective basic training and continuous professional and vocational development 2016. https://www.hee.nhs.uk/our-work/hospitals-primary-community-care/mental-health-learning-disability/mental-health/dementia.
19. World Health Organization. Global age-friendly cities: A guide: World Health Organization, 2007.


For peer review only

20. Crampton J, Dean, J., Eley, R., AESOP Consortium. Creating a dementia-friendly York: Joseph Rowntree Foundation York, 2012.
21. Mitchell L, Burton E, Raman S. Dementia-friendly cities: Designing intelligible neighbourhoods for life. *Journal of Urban Design* 2004;**9**(1):89-101 doi: 10.1080/1357480042000187721published Online First: Epub Date]|.
22. Mitchell L, Burton E. Designing dementia-friendly neighbourhoods: helping people with dementia to get out and about. *Journal of Integrated Care* 2010;**18**(6):11-18
23. https://www.dementiafriends.org.uk/. Dementia Friends. Secondary Dementia Friends.
24. Joseph Rowntree Foundation. Developing a national user movement for people with dementia - learning from the Dementia Engagement and Empowerment Project (DEEP). 2015
25. Royal College of Nursing. Dementia: Commitment to the care of people with dementia in hospital settings. London, 2013.
26. Department of Health. Prime Minister's challenge on dementia: Delivering major improvements in dementia care and research by 2015. In: Health Do, ed. London, 2012.
27. Mayrhofer AG, C.; Holman, C. Establishing a community of practice for dementia champions (innovative practice). *Dementia (London, England)* 2014 doi: 10.1177/1471301214542534published Online First: Epub Date]|.
28. Mayrhofer A, Goodman C, Sharpe R, Dye H. Dementia Education in Hertfordshire and Bedfordshire: An organisational audit commissioned by Health Education East of England. Centre for Research in Primary and Community Care (CRIPACC), University of Hertfordshire. Hatfield: University of Hertfordshire, 2014.
29. Dewing JD, Saskia. What is the current state of care for older people with dementia in general hospitals? A literature review. *Dementia* 2014:1471301213520172
30. Handley M, Bunn F, Goodman C. Interventions that support the creation of dementia friendly environments in health care: protocol for a realist review. *Systematic reviews* 2015;**4**(1):1
31. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC medicine* 2013;**11**(1):21
32. Spencer; Ra. Qualitative data analysis for applied policy research. *The qualitative researcher's companion* 2002:305-29
33. Pawson R. Evidence-based policy: A realist perspective: Sage publications, 2006.
34. Kitwood T, Bredin K. Evaluating dementia care the DCM method: Bradford, England: Bradford Dementia Research Group, Bradford University, 1997.
35. Wong G, Greenhalgh T, Pawson R. Internet-based medical education: a realist review of what works, for whom and in what circumstances. *BMC medical education* 2010;**10**(1):12
36. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review–a new method of systematic review designed for complex policy interventions. *Journal of health services research & policy* 2005;**10**(suppl 1):21-34
37. Williams R. Hospital programme for dementia-specific care: Using detailed observations of patients' experiences, Barbara Hodkinson developed the Butterfly Scheme to identify people with memory impairment and improve their care. She tells Ruth Williams how it works. *Nursing older people* 2011;**23**(7):14-17
38. Banks PW, A.; Henderson, J.; Sharp, B.; Brown, M.; Oliver, J.; Marland, G. Enriching the care of patients with dementia in acute settings? The Dementia Champions Programme in Scotland. *Dementia (London, England)* 2014;**13**(6):717-36 doi: 10.1177/1471301213485084published Online First: Epub Date]|.
39. Crabtree J, Mack J. Developing champions to enhance the care of people with dementia in general hospitals. *Nursing times* 2010;**106**(48):13-14
40. Ellison S, Watt G, Christie I. Evaluating the impact of the Alzheimer Scotland Dementia Nurse Consultants/Specialists & Dementia Champions in bringing about improvements to dementia care in acute general hospitals. 2014

For peer review only

41. Waugh AM, G.; Henderson, J.; Robertson, J.; Wilson, A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-9 doi: 10.7748/ns2011.04.25.32.44.c8452published Online First: Epub Date]|.
42. Wilkinson I, Coates A, Merrick S, Lee C. Junior doctor dementia champions in a district general hospital (innovative practice). *Dementia (London, England)* 2015 doi: 10.1177/1471301215584083published Online First: Epub Date]|.
43. Elliot R, Adams J. The creation of a Dementia Nurse Specialist role in an acute general hospital. *Journal of psychiatric and mental health nursing* 2011;**18**(7):648-52 doi: 10.1111/j.1365-2850.2011.01771.xpublished Online First: Epub Date]|.
44. Griffiths P, Bridges J, Sheldon H, Thompson R. The role of the dementia specialist nurse in acute care: a scoping review. *Journal of clinical nursing* 2014
45. Holmes J, Montaňa C, Powell G, et al. Liaison Mental Health Services for Older People: A Literature review, service mapping and in-depth evaluation of service models. *Produced for the National Institute for Health Research Service Delivery and Organisation programme* 2010
46. Baldwin R, Pratt H, Goring H, Marriott A, Roberts C. Does a nurse-led mental health liaison service for older people reduce psychiatric morbidity in acute general medical wards? A randomised controlled trial. *Age and ageing* 2004;**33**(5):472-78
47. Waller S. Redesigning wards to support people with dementia in hospital: Sarah Waller describes a programme that is bringing staff and patients together to create more welcoming and inspiring therapeutic environments. *Nursing older people* 2012;**24**(2):16-21
48. Goldberg S, Whittamore KH, Pollock K, Harwood RH, Gladman JR. Caring for cognitively impaired older patients in the general hospital: a qualitative analysis of similarities and differences between a specialist Medical and Mental Health Unit and standard care wards. *Int J Nurs Stud* 2014;**51**(10):1332-43 doi: 10.1016/j.ijnurstu.2014.02.002published Online First: Epub Date]|.
49. Goldberg S, Bradshaw, Lucy E; Kearney, Fiona C; Russell, Catherine; Whittamore, Kathy H; Foster, Pippa ER; Mamza, Jil; Gladman, John RF; Jones, Rob G; Lewis, Sarah A. Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial). *BMJ (Clinical research ed.)* 2013;**347**
50. Spencer K, Foster, P., Whittamore, K. H., Goldberg, S. E., Harwood, R. H. Delivering dementia care differently--evaluating the differences and similarities between a specialist medical and mental health unit and standard acute care wards: a qualitative study of family carers' perceptions of quality of care. *BMJ open* 2013;**3**(12):e004198 doi: 10.1136/bmjopen-2013-004198published Online First: Epub Date]|.
51. Nichols JN, Heller KS. Windows to the heart: Creating an acute care dementia unit. *Journal of palliative medicine* 2002;**5**(1):181-92
52. Zieschang T, Dutzi I, Müller E, et al. Improving care for patients with dementia hospitalized for acute somatic illness in a specialized care unit: a feasibility study. *International Psychogeriatrics* 2010;**22**(01):139-46
53. Scerri A, Innes A, Scerri C. Discovering what works well: exploring quality dementia care in hospital wards using an appreciative inquiry approach. *Journal of clinical nursing* 2015
54. Waugh A, Marland G, Henderson J, Robertson J, Wilson A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-49
55. Mayrhofer A, Goodman C, Holman C. Establishing a community of practice for dementia champions (innovative practice). *Dementia* 2015;**14** doi: 10.1177/1471301214542534published Online First: Epub Date]|.

For peer review only

56. Griffiths A, Knight A, Harwood R, Gladman JR. Preparation to care for confused older patients in general hospitals: a study of UK health professionals. *Age and ageing* 2013:aft171
57. Baillie L. An Evaluation of Barbara's Story: Final Report. London: Guy's and St Thomas' NHS Foundation Trust, London South Bank University, 2015.
58. Dowding D, Lichtner V, Allcock N, et al. Using sense-making theory to aid understanding of the recognition, assessment and management of pain in patients with dementia in acute hospital settings. *International Journal of Nursing Studies* 2016;**53**:152-62
59. Schneider J, Scales K, Bailey S, Lloyd J. Challenging care: the role and experience of health care assistants in dementia wards. *National Institute for Health Research Service Delivery and Organisation programme. Available online at http://panicoa. org. uk/sites/assets/challenging_care. pdf [Accessed August]* 2010
60. Bray J, Evans S, Bruce M, et al. Improving activity and engagement for patients with dementia. *Nursing older people* 2015;**27**(8):22
61. Brooker DM, Sarah; Evans, Simon; Carter, Christine; Bruce, Mary; Thompson, Rachel. RCN Development Programme: Transforming Dementia Care in Hospitals Evaluation Report. 2014
62. Duffin C. Raising awareness to support people with dementia in hospital: A film produced to train staff at one trust has had such a positive effect that it is to be used nationwide. Christian Duffin reports on this and other measures to improve care. *Nursing older people* 2013;**25**(5):14-17
63. Edvardsson D, Sandman PO, Rasmussen B. Forecasting the ward climate: a study from a dementia care unit. *Journal of clinical nursing* 2012;**21**(7-8):1136-114
64. Gonski PN, Moon I. Outcomes of a behavioral unit in an acute aged care service. *Archives of gerontology and geriatrics* 2012;**55**(1):60-65
65. Luxford K, Axam A, Hasnip F, et al. Improving clinician–carer communication for safer hospital care: a study of the 'TOP 5'strategy in patients with dementia. *International Journal for Quality in Health Care* 2015:mzv026
66. Moyle W, Borbasi S, Wallis M, Olorenshaw R, Gracia N. Acute care management of older people with dementia: a qualitative perspective. *Journal of clinical nursing* 2011;**20**(3-4):420-28
67. Rösler A, von Renteln-Kruse W, Mühlhan C, Frilling B. Treatment of dementia patients with fracture of the proximal femur in a specialized geriatric care unit compared to conventional geriatric care. *Zeitschrift für Gerontologie und Geriatrie* 2012;**45**(5):400-03
68. Upton. An evaluation of quality and cost effectiveness of a newly defined suite of care interventions for patients with dementia and their carers in the acute hospital setting developed by The Royal Wolverhampton Hospitals NHS Trust REPORT PHASE 2 – Volume 1: University of Worcester, 2012.
69. Enns E, Rhemtulla R, Ewa V, Fruetel K, Holroyd-Leduc JM. A controlled quality improvement trial to reduce the use of physical restraints in older hospitalized adults. *Journal of the American Geriatrics Society* 2014;**62**(3):541-45 doi: 10.1111/jgs.12710published Online First: Epub Date]|.
70. Harwood RH PD, King N, Edwards G, Hammond S, Howe L, et al. . Development of a Specialist Medical and Mental Health Unit for Older People in an Acute General Hospital. MedicalCrises in Older People Discussion Paper Series. Issue 5, November 2010., 2010.
71. Goldberg SE, Whittamore KH, Pollock K, Harwood RH, Gladman JRF. Caring for cognitively impaired older patients in the general hospital: A qualitative analysis of similarities and differences between a specialist Medical and Mental Health Unit and standard care wards. *International Journal of Nursing Studies* 2014 doi: 10.1016/j.ijnurstu.2014.02.002published Online First: Epub Date]|.
72. Williams AM, Toye C, Deas K, Fairclough D, Curro K, Oldham L. Evaluating the Feasibility and Effect of Using a Hospital-Wide Coordinated Approach to Introduce Evidence-Based Changes for Pain Management. *Pain Management Nursing* 2012;**13**(4):202-14 doi: 10.1016/j.pmn.2010.08.001published Online First: Epub Date]|.


For peer review only

73. Goldberg SE, Bradshaw LE, Kearney FC, et al. Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: Randomised controlled trial (NIHR TEAM trial). *BMJ (Online)* 2013;**347**(7917) doi: 10.1136/bmj.f4132published Online First: Epub Date]|.
74. von Renteln-Kruse W, Neumann L, Klugmann B, et al. Geriatric Patients With Cognitive Impairment: Patient Characteristics and Treatment Results on a Specialized Ward. *Deutsches Ärzteblatt International* 2015;**112**(7):103
75. Turner A, Eccles FJ, Elvish R, Simpson J, Keady J. The experience of caring for patients with dementia within a general hospital setting: a meta-synthesis of the qualitative literature. *Aging & mental health* 2015:1-11
76. Digby R, Lee S, Williams A. Interviewing people with dementia in hospital: recommendations for researchers. *Journal of clinical nursing* 2016
77. Digby R, Lee S, Williams A. The experience of people with dementia and nurses in hospital: an integrative review. *Journal of clinical nursing* 2016
78. Borbasi S, Jones J, Lockwood C, Emden C. Health Professionals' Perspectives of Providing Care to People with Dementia in the Acute Setting: Toward Better Practice. *Geriatric Nursing* 2006;**27**(5):300-08 doi: 10.1016/j.gerinurse.2006.08.013published Online First: Epub Date]|.
79. Dewing J. Special observation and older persons with dementia/delirium: a disappointing literature review. *International journal of older people nursing* 2013;**8**(1):19-28

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Figure 1: Flow diagram of searches and evidence retrieval

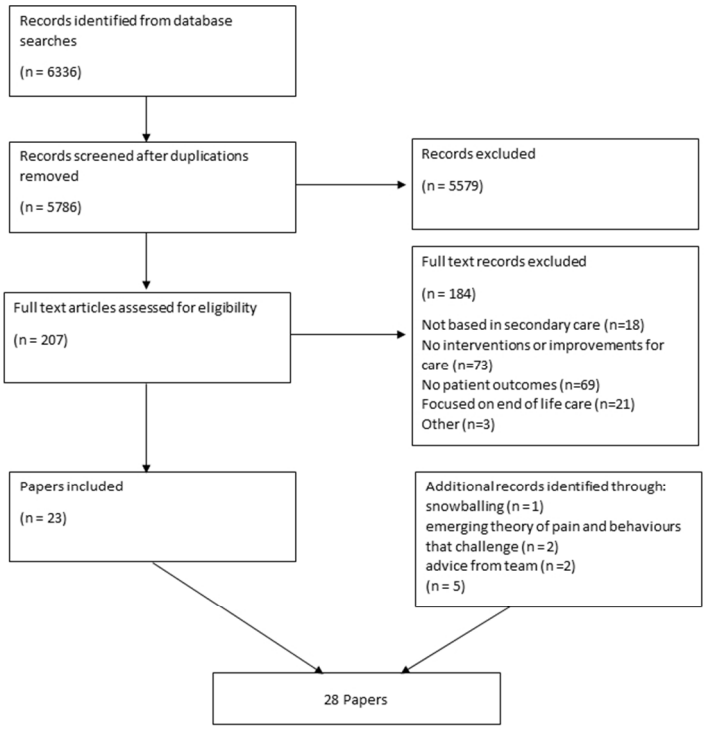


Figure 1: Flow diagram of searches and evidence retrieval

210x300mm (96 x 96 DPI)

Supplementary file 1

Evidence for theory area 1: To support staff awareness and learning

| Paper | Example Evidence | Key Points and emerging CMOs |
|---|---|---|
| Baillie (2015) | "I think the Barbara's Story made me more aware of them so I go to help them where perhaps I may not necessarily have noticed them before. (Therapists1)" (p26) | Raising awareness to recognise signs and symptoms of dementia |
| | "After seeing the video it makes those kinds of patients easier to speak with and it also reassures you, so for example in the video it talks about not taking them out of their own reality, and I think that just reassures people that you can distract them and not 'lie' to them and that's okay, and I think that's reassuring to people that don't know that much about dementia." (p46) | Training to improve confidence in working with people living with dementia<br><br>Reassurance from examples in training of how to work well with people living with dementia |
| | "Staff remembered Barbara being 'lost', 'confused', 'vulnerable', 'scared' and 'worried'. They engaged with her as a person who could be a family member… Some staff specifically related Barbara's Story to a family member, which personalised the film's story… There was also acknowledgement that any of us could find ourselves in a similar situation." (p24) | Training that developed empathy helped staff relate to people living with dementia as family members |
| | "Barbara's Story enabled staff to see her healthcare experience from her perspective and the behaviour shown in the film prompted staff to reflect on their own behaviour and that of colleagues." (p23) | Shown experience from patient's viewpoint to understand how need to adapt care practices |
| | "In most focus groups, staff discussed how their own interactions with patients and behaviour had changed since watching Barbara's Story, and they often referred to changes they had observed in other staff too. Areas discussed included: giving more time to patients, improved communication, giving more information, and assisting patients who are looking lost." (p25) | Changes staff implemented after training; time for patients, better communication, information, recognising and acting upon distress and confusion. |
| | Some participants considered that Barbara's Story had raised the profile of initiatives | Training supporting and promoting the use of other |

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| | and other work that was already in place for people with dementia, further reinforcing and helping developments to embed in the Trust, such as dementia study days and dementia champions and use of the forget-me-not." (p29) | resources. |
| | "Staff related how they listened to patients with a history of dementia, taking their physical symptoms more seriously, rather than attributing them to their dementia: 'we will now investigate it a little bit more [...] any physical symptoms we will take seriously' [rather than attributing it to their dementia or mental health condition (Nurse10). Similarly, in relation to behaviour, another nurse said:<br>I think it's really important for staff to remember not to play a part in that stigma and not to make excuses if they're upset or aggressive, not to put it down to their condition, sometimes they are just genuinely wanting something or upset. (Nurses8)" (p51) | Staff reported changes to practices following training. Understanding behaviours as communication of other needs rather than symptoms of dementia. |
| | "Those who had used This is me were great advocates for the tool and the difference it made in practice:<br>I saw it once in practice and I thought to myself, this is the best thing that anyone has ever done because it just made the care you gave so personalised and I remember the patient and it said in the notes, loves Coronation Street and EastEnders. So at 7.30pm I'd go and put on Coronation Street, just because I knew about it. (Nurses4)<br>… It's nice to know a bit more about them, what they like and don't like, even if it's just down to how they like their tea or they don't like tea. (Nurses6)" p53 | Use of biographical tool to understand the preferences and routines of the patient. |
| | In one focus group, an example of the benefits of This is me was explained:<br>She [patient with dementia] was in for less than three days, got home, she wasn't a delayed discharge but my point had been if This Is me hadn't been filled in and she was distressed and constantly calling, they'd have given her [medication], shut her up, then she'd have been over-sedated, she wouldn't have been eating and drinking, her delirium would have been worse. (Nurses4) | How not knowing about the patient leads to distressed behaviours that might have adverse results such as inappropriate medication, poor nutrition and hydration, and increased severity of delirium. |
| Banks | "[this is me] By having this document we have reduced the amount of medication the | Resources that support knowledge of the patient |

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| (2014) | patient receives in hospital. Staff are much more likely to look into why the patient is behaving this way rather than get them prescribed medication. This in turn has reduced the number of falls during the day, therefore reducing the number of fractures and increased stays in hospital. P727<br><br>The first change we made was to stop separating the patient with dementia from the relative during the admission process. ... I think the relatives feel more valued as a carer and the importance of their role in looking after their relative with dementia is recognised. The patients are also much more relaxed to have familiar faces around so the admission process has become much smoother for everyone including the staff p727<br><br>I have tried to take back to the ward with me topics that I have learned and shared with other members of staff. This has been an eye opener as some staff are not keen to accept change and question everything that I have tried to do and don't seem to see the need for change. P728 | reduce adverse events such as inappropriate medication, falls, and increased length of stay. Resources that support knowledge of the patient encourage staff to understand behaviour as a form of communication.<br><br>Changing processes and procedures that understand the needs of people living with dementia to reduce patient distress and improve carer satisfaction.<br><br>Difficulty in getting staff to change practices if they do not recognise the need to change practices. |
| Brooker (2014) | "[Dementia awareness training] It has made a big difference to how staff respond to the behaviour of patients with dementia, as it has increased understanding and awareness. For example, there is now a greater focus on occupying patients with activities to reduce behaviour that challenges, and staff are now seen to be walking around with patients with dementia who are wandering when previously they would have told them to sit back down." P48 | Dementia awareness training improves staff understanding of how to better support people living with dementia. Understand the need for providing activities to reduce onset of behaviours that challenge and adapting way of working. |
| Dowding (2016) | Participants discussed how pain may be intermittent and fluctuate, often only being present when patients are engaged in certain activities. ''often the doctors will go round and they'll ask the patient in their bed or in their chair, ''Oh, are you alright? Any pain anywhere?'', ''No, I'm fine''. As soon as we [physiotherapists] come, get them up on it, ''Oh, oh, that really hurts''.[H1, physiotherapist] p156 | Need to understand people living with dementia have difficulty communicating their needs (e.g. pain relief) and will have problems recalling and describing experiences of pain. |

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| | As with other patients, one of the challenges faced by clinicians is the initial recognition of whether or not a patient may be in pain at all; for a variety of reasons patients (including those with cognitive impairment) may not be able to verbally express they have pain, and clinicians often find it challenging to interpret behavioural signals which may be 'atypical' in nature. p157<br><br>One of the key factors in assessing and managing pain is the ability to build a 'picture' or narrative of the patient case; which is used as the basis for the interpretation of cues, to try and 'make sense' of a situation. Participants highlighted the importance of building patterns of information cues and patient behaviour, to help inform their decision making. This narrative occurred over time (an issue which arose in other themes from the data), trying to link different events over the trajectory of a patient stay, to help test 'guesses' and form the basis of trial and error approaches to management. P157<br><br>From the observations it appeared that pain recognition, assessment and management was carried out over time, by many individuals. Rather than being under the control of one specific nurse or other health care professional, it could be characterized more as a process of distributed work, which is time dependent. This is reflected in the comments in interviews, which highlight how there is a division of labour in the hospital ward; there numerous people with different professional roles who are all involved in the care of each patient, each with specific duties, responsibilities and powers. In turn, these roles often governed which part of the pain recognition, assessment and management process they participated in, and how they communicated their findings. p158 | Challenges for staff to understand patient needs.<br><br>Getting to know the needs of the patient through time and continuity in their care.<br><br>Context of ward where responsibilities for the patient's needs are across a number of staff; those who recognise the need may not be able to directly address the need. Importance of communication with colleagues. |
| Duffin (2013) | 'Some people have been moved to tears by the DVDs,'(outcome) says Ms Karasu. 'The films resonate with them. Sometimes you see a look on their face and you can tell they are thinking: "I never thought of that." (reasoning) P16<br><br>In one training session nurses, doctors and other staff wear specially designed goggles that restrict their vision, and put on a jacket which has small splints inserted in the arms | Emotional engagement with training and realisation of the patient's experiences of care.<br><br>Experiential learning triggering realisation of patient |

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| | to restrict movement of their upper body. This is to help staff understand the physical constraints faced by some older people. Darlene Romero, a matron across the trust's three older people's wards, who delivers the training, says: 'It's a real eye opener, and makes you realise how difficult it can be to go to the toilet. P16<br><br>A laminated symbol of a forget-me-not is placed above the beds of all patients with dementia, and a similar motif is put on their casenotes, so that any health worker who comes into contact with them is aware of their condition. Ms Wood says: 'It shows our team that they need to adapt because the person with them has a cognitive impairment. If someone goes to have an X-ray, for example, the team would see the forget-me-not symbol and they would know that this person may not just jump up onto the couch and be ready. They will need to provide more explanation and perhaps to stay a bit calmer than they would with other patients to show extra sensitivity. P17 | needs.<br><br>Identifying a patient has dementia, staff recognising they need to adapt care to be appropriate to the needs of the patient. |
| Edvardsson (2012) | The subtle initial expression of emerging needs were not picked up by staff as they were absent and the expression of unmet needs could escalate to become behavioural alterations as the need remained unsatisfied. When staff finally came about, they were observed to interpret the behaviour as 'disruptive' or 'disturbing' as they lacked the initial interpretative cues that could explain the behaviour. As a consequence, care became very much reactive, as staff had to come up with acute solutions to full-blown situations for which they lacked the insight and an interpretative framework. P6 | Care becomes reactive when behaviour is misinterpreted. Underlying causes not investigated. |
| Ellison (2014) | Colleagues reported improved skills, knowledge and understanding as well as improved confidence in caring for people with dementia as a result of the training and working alongside a Champion. Colleagues also reported changes in their practice as a result of training, for example:<br>spending more time with people with dementia on a one to one basis to provide more individualised care; more effective communication as a result of a better understanding of the needs of people with dementia; involving carers more proactively; understanding | Training supported by a Champion to improve knowledge and understanding of dementia and confidence to work well with people living with dementia. Staff reported changes to care practices. |

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| | the importance of personal care plans and documentation; being more aware of the impact of the environment on people with dementia; being more proactive in providing additional assistance to people with dementia; being prepared to challenge bed moves involving people with dementia when there was no clinical need; increased awareness of signs of stress and distress and seeking to identify the cause rather than resort to use of sedatives. p51 | Staff seeking to address underlying need of people living with dementia rather than treating behaviour with medication. |
| | The primary actions undertaken in this respect have been the implementation of person-centred care planning through use of the 'This is Me' document initially, and subsequent development and implementation of 'Getting to Know Me'. Many DCs have played a key role in implementing and trying to embed these documents through introducing it to their team and training staff in its application. … Use of GTKM allows staff to find out more about the patient and their preferences and is generally considered a useful tool in supporting improved person-centred care for people with dementia. Comments from Champions and their colleagues working in acute settings suggest that use of person-centred plans like this represents a departure from the norm for them in terms of the information they are used to collecting and the conversations they are used to having with patients. Examples were cited where staff have used GTKM more effectively minimise stress and distress, reporting how the information they gained about the patient through the assessment had supported them to recognise and respond more effectively to distressed behaviour. p53 | Use of biographical tools to support person centred care practices that reduce distress.<br>Role of champions in supporting implementation of tool. |
| | In interviews DCs frequently cited the role they have played in influencing the behaviour of colleagues, for example by challenging inappropriate use of language when speaking to or speaking about people with dementia. p54 | Champions role in addressing negative staff attitudes towards people living with dementia. |
| | "Staff's attitudes have changed hugely in A&E [as a result of DC's awareness raising of how noise and activity can cause distress] – you used to see someone with dementia and there would be 2 or 3 nurses with the one patient, each doing something else and | Champion supports staff to understand difficulties faced by people living with dementia. Staff adapt |

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| | the poor patient... now you see them going in one person at a time, calmer more quietly."p56 | practices to recognise and support difficulties. |
| Galvin (2010) | [post training] The staff also recognized the need for improved communication skills with the patient, such as sitting and talking clearly, using nonverbal clues, and asking permission to touch the patient in order to improve care. | Training for staff to recognise the need to change practices.<br><br>Additional evidence of how training encouraged staff to implement new resources to improve care of people living with dementia (activity packs, volunteers, identification method for patients at risk of leaving the ward). |
| Goldberg (2014) | Staff also appeared more accepting and understanding of mental health problems and patients on the Unit were more likely to raise concerns about their mental health and these would be responded to by staff. This could be because staff were more aware of mental health needs, because they had more conversations with staff in general (and thus the opportunity to raise such concerns) or it could be because they were cared for on a ward where all patients were cognitively impaired. (p1337)<br><br>The Unit provided a greater focus on the mental health needs of patients. Staff were more often observed assessing patients' cognitive abilities (using standardised tools and by questioning) than on standard care. P1337<br><br>Sometimes, skilled care on the Unit was not evident to observers, as patients who had the potential to exhibited distress behaviour were calm. In this observation Alex has been calmly walking up and down the ward for over an hour. A member of staff has always been walking with him and talking to him. Alex's aggression was only evident when something unexpected happened. P1337<br><br>Individual attention was given to patients at other times on the Unit with staff getting patients drinks or snacks outside of the meal and drink rounds and using touch when | Awareness and understanding of dementia led staff to address patient psychological and mental health needs.<br><br>Use of assessment tools to understand patients' cognitive abilities.<br><br>Supporting patient choice and independence to reduce distress and the onset of behaviours that challenge.<br><br>Staff working outside of ward routine to meet individual needs. |

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| | interacting with patients. P1338<br><br>However, the psychological needs of the patients on the Unit were high and a minority of patients would call out persistently for long periods of time. Staff would try to comfort or distract them… But the calling out would resume once the staff member left the patient and the conflicting demands on time meant staff would sometimes ignore their cries and attend to other patients, staff or documentation… Delivering care to patients with these behaviours could be exhausting and sometimes, particularly towards the end of a 'long day' (12 1/2 h shift), staff would ignore patients. P1338 | Constraints to addressing patient needs when unable to find out the cause, conflicting demands on staff time, and staff fatigue. |
| Gonski (2012) | Staff members stated that they were sufficiently trained and a majority (n = 11) were able to confidently manage the behavioral problems. The respondents reported that they were able to build therapeutic relationships with both the patients and the carers and were also happy to provide help for both parties. In terms of communication, the nurses were very confident they could communicate with the patients, and therefore were able to interpret individual's needs. P62 | Training supports staff confidence to work with people living with dementia who have behaviours that challenge. Staff ability to communicate well with patients helps them build relationships with patients and understand their needs. |
| Luxford (2015) | Early in the implementation period, a few clinicians reported difficulty in translating the carers' tips into a workable strategy for the hospital environment as they lacked confidence to write strategies based on 'non-clinical' tips. This issue was addressed through further training and the development of lanyards for clinicians to use which demonstrated how to write an effective TOP 5. P5<br><br>After implementing TOP 5, the majority of clinicians reported agreeing or strongly agreeing that TOP 5 was easy to use (91%), not time consuming (70%), decreased patient agitation and distress (74%), resulted in decrease use of restraint—physical or chemical (61%)—and made it easier to relate to carers (89%). P5 | Use of biographical tool supported by champions, training, and examples of how to implement information into care plan.<br><br>Use of biographical tool perceived to reduce patient agitation and distress and the use of restraints. |
| Nichols (2002) | "We built an interdisciplinary team that looks at the patient and the caregiver as a unit, works with them, and responds to the patient's behaviour as meaningful behaviour that needs to be understood. We understand that dementia patients have special needs. | Working with carer to understand patient's needs. Understanding that behaviour is a communication of an unmet need. |

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| | Using a team approach has allowed us to meet those needs in an acute care hospital." p186 | |
| Scerri (2015) | Care worker (S32): I was thinking about this particular patient who did not need physiotherapy because he was here for respite care. He used to turn to all the staff to ask questions .. So every time I used to engage in a conversation with him and try to first calm him and reassure him because he was panicking and living in a situation as if it is real for him. P6 | Recognising patient needs and addressing them to reassure. Understanding from patient perspective. |
| Schneider (2010) | We found that HCAs continuously ensured that patients were as comfortable as possible, some going out of their way to achieve this. One worker was even known to have sewed and adapted patients' clothing to maximise their comfort (and staff convenience, because this prevented frequent changes of clothing). Efforts were made to overcome language barriers between staff and non-English speaking patients and, when patients were distressed, HCAs often comforted them with actions as well as words: The male patient who becomes very distressed and cries was comforted greatly by H/CO who warmly cuddled up next to him, whilst on his observation, putting her arm around him and letting him snuggle into her, putting his head on her chest. (Fieldnote, Ward C) p28<br><br>We concentrate more, as you get to know the patients, the more you know their ways, you know their habits and if they've got a bad tummy and things like that and you get to know them; the job comes easier when you get to know them. It doesn't stop you getting hit sometimes, but you're aware of, you just get to know them and understand them a bit more. P47<br><br>"Invoking their practical autonomy, the HCAs also made minor adaptations within routines to suit individual patients. For example, medications were administered to all patients at approximately the same times every day on each ward, rather than being doled out individually; this ensured that every patient received his or her medication, as well as conserving staff time. However, within this routine, HCAs who were 'running' | Recognising and addressing patient needs to improve comfort for patients and benefit staff workload.<br><br>Importance of getting to know patients and benefits to workload.<br><br>Personalising tasks for needs of patients. |

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| | the medications would often make small concessions, for example by taking extra time to gain the trust of individual patients." P 49 | |
| Spencer (2013) | Carers of patients with MMHU described staff as being 'well prepared' for dealing with confused patients, displaying patience and compassion. Respondents noted that patients who liked to wander were guided by staff when walking up and down rather than constantly being returned to their bed space, a behaviour observed by carers on standard care wards. P3<br><br>"Participants felt that staff had little understanding and limited training in dementia care, which carers felt resulted in patients being ignored, shouted at or threatened when staff were faced with uncooperative or challenging situations." P3 | Staff who have understanding of dementia and dementia care can meet the needs of patients.<br><br>Where staff lack understanding of behaviours that challenge they misinterpret them and attribute the problem to the patient, leading to poor care. |
| Waller (2015) | Many of the environmental changes appear to have occurred as a consequence of the training that teams received before they started planning their projects. For example changes in staff attitudes such as investing in table cloths, laying tables, and purchasing coloured crockery, as well as increases in activities for patients such as the provision of newspapers or implementation of therapy hours, were reported; in the words of one team member, it is 'not just about the colour of the paint'. P64<br><br>Making spaces seem smaller and more familiar, and reducing the numbers of decisions that have to be made by patients in finding their way to places such as the toilet, the dining room or their own bed space, seems to significantly reduce agitation. P65 | Staff training helps staff recognise the needs of people living with dementia and make adaptions.<br><br>Changes that recognise the difficulties of people living with dementia will help reduce distress. |
| White (2016) | Patients with any form of BPSD during their admission were five times more likely to have an antipsychotic prescribed during the admission (OR 4.99, 95% CI 1.15, 21.70, p=0.032). Antipsychotic prescription was five times more likely in people who experienced hallucinations (OR 5.04, 95% CI 2.10, 12.06, p≤0.001) or activity disturbances (OR 5.71, 95% CI 2.22, 14.70, p≤0.001) and seven times more likely with aggressive behaviours (OR 7.70, 95% CI 2.25, 26.31, p=0.001). Patients were three times more likely to have an antipsychotic prescribed when they experienced sleep | Behaviours that challenge increase likelihood of antipsychotic prescription. |

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| | disturbance (OR 3.35, 95% CI 1.45, 7.79, p=0.005).<br><br>In total, 55% of participants received non-pharmacological management during their admission. The most commonly used techniques were psychosocial interventions (36%) and staffing (17%) (Table 2). We found no evidence in the nursing or medical notes of ongoing monitoring or review of the effectiveness of these non-pharmacological interventions, or of a systematic way of using these techniques. | Lack of monitor of non-pharmacological management of behaviours that challenge so difficult to know effectiveness. |
| Williams (2011) | We are testing a REACH education programme for domestic assistants and housekeepers… They had not considered the positive impact they could have in contributing to care and, without exception, were delighted to support the initiative. P15<br><br>REACH helps all staff to understand the cognitive difficulties experienced by people with dementia. It enables them to contribute in their role and promotes pride in the part they play in care. p15<br><br>Carers feel relieved that their loved one's condition is recognised and that hospital staff know how to respond to them, while the carers' sheet allows families to pass on crucial information and tips that will keep patients safe and improve their care'. P17 | Understanding the problem, knowing how can make a difference to patient experience and being able to take pride in work.<br><br>Working with carers to get to know the patient and know strategies that work well to improve patient safety. |

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# Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review



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Title Page

**Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review**

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**Abstract**

Objectives: To identify features of programmes and approaches to make healthcare delivery in secondary healthcare settings more dementia friendly, providing a context-relevant understanding of how interventions achieve outcomes for people living with dementia.

Design: A realist review conducted in three phases (1) stakeholder interviews and scoping of the literature to develop an initial programme theory for providing effective dementia care; (2) structured retrieval and extraction of evidence; (3) analysis and synthesis to build and refine the programme theory.

Data sources: PubMed, CINAHL, Cochrane Library, NHS Evidence, Scopus, grey literature.

Eligibility criteria: Studies reporting interventions and approaches to make hospital environments more dementia friendly. Studies not reporting patient outcomes or contributing to the programme theory were excluded.

Results: Phase 1 combined findings from 15 stakeholder interviews and 22 publications to develop candidate programme theories. Phases 2 and 3 identified and synthesised evidence from 28 publications. Prominent context-mechanism-outcome configurations were identified to explain what supported dementia friendly health care in acute settings. Staff capacity to understand the behaviours of people living with dementia as communication of an unmet need, combined with a recognition and valuing of their role in their care prompted changes to care practices. Endorsement from senior management gave staff confidence and permission to adapt working practices to provide good dementia care. Key contextual factors were the availability of staff and an alignment of ward priorities to value person-centred care approaches. Preoccupation with risk generated responses that were likely to restrict a patient's choices and increase their distress.

Conclusions: This review suggests strategies such as dementia awareness training alone will not improve dementia care or outcomes for patients with dementia. Instead, how staff are supported to implement learning and resources by senior team members with dementia expertise is a key component for improving care practices and patient outcomes.

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**Strengths and limitations of this study**

- Applying realist methods enabled a theory-driven explanation of how dementia friendly health care can be supported in hospital settings
- The process of the review facilitated the development of a new programme theory, which can be used to inform future initiatives that support people with dementia in hospital environments
- The involvement of stakeholders from the outset ensured the plausibility and relevance of the findings for hospital environments
- The extent of evidence to support some elements of the programme theory was limited, especially where interventions lacked specificity about process and patient outcomes.

**Key words**

People living with dementia, hospitals, dementia, realist review, dementia friendly

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## INTRODUCTION

There is increasing recognition that hospital staff and services need to understand the complexity of caring for and treating people living with dementia [1]. At any one time, 25% of hospital beds are used by people living with dementia, rising to a higher proportion on some wards [2]. Co-morbidities are common and many people are admitted to hospital for reasons not directly related to their dementia [3-5]. Healthcare outcomes for people living with dementia are variable across the country and are inequitable when compared to outcomes for people without cognitive impairments [5]. Adverse incidents occurring during admissions, such as falls, poor nutrition and hydration, infections, and the onset of delirium, contribute to longer stays and reduced functional abilities which may result in admission to a care home [6-8].

A number of factors may impact on the disparity of health outcomes for people living with dementia including: a lack of focus and leadership for dementia in hospitals [5]; healthcare staff who have inadequate knowledge and training in dementia and dementia care [9, 10]; difficulties faced by healthcare professionals when assessing the risk and benefits of treatment options [11]; widespread use of care practices which are detrimental to people living with dementia, such as the use of antipsychotics for behavioural management [12]; stigma and discrimination towards people living with dementia [13, 14]; and confusing, unsafe environments [15]. The National Dementia Strategy [16] aimed to improve the quality of care for people living with dementia in general hospitals through leadership that addresses quality improvements in dementia care, defined care pathways, and the use of liaison mental health teams. It also highlighted the importance of education and training to break down the stigma associated with dementia and to develop dementia awareness within the healthcare workforce. To address these ambitions, interventions have been designed and implemented with the aim of creating dementia friendly health care in hospitals [17, 18].

### Dementia Friendly

The concept of dementia friendly developed from initiatives to promote age-friendly communities [19]. It was first used to describe physical and social environments that promoted inclusion, acceptance and accessibility for people living with dementia [20, 21] and includes initiatives supporting the independence and safety of people living with dementia [22]. In the UK this includes the Dementia Friends initiative [23] and the Dementia Engagement and Empowerment Project (DEEP) [24].

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At the patient level, dementia friendly healthcare is the practice and organisation of care that is aware of the impact dementia has on a person's ability to engage with services and manage their health. It promotes the inclusion of people living with dementia and their carer in treatments, care decisions and discussions, with the aim of improving outcomes for the patient and carer [16, 17, 25-27].

Interventions to promote dementia friendly healthcare environments have been diverse in terms of their design and application in practice [27-29]. This review of the evidence acknowledges that the effectiveness of programmes to address the known problems of being a patient with dementia is contingent on multiple factors such as staff knowledge and skills in dementia care, the care environment, and the competing demands on staff time and attention. The review objectives were:

1. To identify how dementia friendly interventions in hospital settings are thought to achieve the desired patient and carer outcomes
2. To develop evidence-based explanations to understand what it is about dementia friendly interventions used in hospitals that works for people living with dementia and their carers, in what circumstances and why.

**Realist Methodology**

Realist review is a theory-led method, that applies the principles of realist theory to evidence review [30, 31]. In realism, causation is considered as generative rather than linear and does not consider that the introduction of an intervention leads directly to change. Instead, a realist approach seeks to explain how the relationship between the resources an intervention introduces and the context it is implemented into influences peoples' reasoning for taking action and generating change [30].

Realist review was appropriate for this study for a number of reasons. The evidence base for dementia friendly interventions is in its early stages. These interventions are complex in both design and implementation; they are multicomponent and rely on human agency that is influenced by individual, service and organisational pressures. Instead of seeing these as confounding factors, realist inquiry acknowledges these features and incorporates them to develop an explanatory account of how different aspects influence reasoning and outcomes [32].

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## METHOD

Realist review methods were used to develop a theoretical understanding of what supports effective dementia care in hospital settings. There were three overlapping, iterative phases: 1) defining the scope of the review informed from key literature and stakeholder interviews; 2) structured searches, screening, and data extraction; 3) analysis and synthesis leading to refinement of the programme theory. A fuller account of the review protocol is available in Handley, et al. [33].

The phases did not follow a linear format, but informed and refined understanding throughout the review, leading to new interpretations and building of evidence. Sources were identified and revisited, new evidence was incorporated, and inclusion criteria reconsidered as new theoretical understanding developed. The RAMESES publication standards informed the preparation of this report and has been vetted against RAMESES criteria (supplementary file 1 and supplementary file 2) [31].

### Changes to the review process

One change to the review process was made subsequent to the published review protocol [33]. The expert steering group workshop was not held. However, emerging findings and the refined programme theory were shared with the with Alzheimer's Society research network monitors (RP, JW, PM) who were volunteer representatives with experience of caring for family members living with dementia. They commented on the resonance and relevance of the inferences that contributed to the developing theory throughout the review process. Review findings were also presented and discussed at a seminar on dementia friendly health care with 75 participants, 19 of whom worked in hospitals. The findings are being taken forward for testing in a realist evaluation.

### Phases of the Realist Review

*Phase one: Defining the scope of the review: concept mining and theory development*

Evidence from interviews with stakeholders and a scoping of the literature was used to identify the range of dementia friendly interventions in health care settings both in the UK and internationally, determine possible theoretical assumptions about how and why interventions were thought to work (or not), and clarify what were understood to be the significant mechanisms for change. Stakeholders, people who had experience in designing, implementing, and using dementia friendly interventions, were identified from knowledge within the team, internet searches, and dementia specific conference abstracts. They were purposively sampled from a range of settings (academia, health care, commissioning, social work, the community) and backgrounds (nursing, education, physiotherapy, research,

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person living with dementia) [33]. Stakeholders were not further involved in the development of the emerging CMOCs or programme theory. Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

Data from interviews and the literature were coded using framework analysis [34] with emerging themes and competing accounts discussed and debated amongst the authors (MH, FB, CG) and with Alzheimer's Society research network monitors (RP, JW, PM). Mapping of this evidence, also shared with the team, demonstrated limited understanding at the point of staff interaction with patients and how this effected patient outcomes. A decision was made to focus the review on how interventions led to patient outcomes. Data from the interviews and literature were scrutinised for demi-regularities (see glossary of realist terms) and informed hypotheses set out in the form of 'If… then statements'. These statements were used to define the conditions thought to be necessary to achieve: 1) staff outcomes, such as taking action to investigate the cause of patient behaviours and applying best practice with people living with dementia; and 2) patient outcomes, such as reduced distress, reduction in adverse incidents, and improved wellbeing. Discussions amongst the authors based on the statements led to the development of a conceptual framework [30]. Three overlapping theoretical propositions were generated to explain what supports the implementation and uptake of interventions that promote dementia friendly health care within a ward based environment.

*Phase two: Retrieval and review*

*Searching for relevant studies*

Informed by the theoretical propositions derived from the work in phase one, search terms were revised. The inclusion/exclusion criteria were refined to focus on studies which reported patient outcomes and provided information about the characteristics and role of change agents (staff who supported the implementation and uptake of interventions).

Searches were limited to 2000 – 2015 to reflect the impact of the work of Kitwood and Bredin [35] on dementia care practices that recognise the importance of person-centred care and the promotion of personhood. In addition to the electronic database searches (box 1), we undertook extensive lateral searching, including forward and backward citations, and contact with experts. Additional searches were performed as emerging themes around the management of pain and behaviours that challenge became apparent. These were purposive searches that applied the same inclusion criteria and supported theory development until theoretical saturation was achieved [36, 37] (box 1).

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Box 1: Phase two search terms and search strategy

Searches initially run September 2015, search alerts scanned to February 2016

Language restricted to English

Date restricted 2000 – 2015

Search terms:

(dementia AND (friendly OR appropriate OR awareness OR champion OR liaison OR ward OR environment OR education OR training OR nurse specialist OR lead* OR person centred care) AND (hospital OR acute care OR secondary care))

Additional search terms developed from findings in phase one:

dementia AND (change agent OR champion OR knowledge transfer OR knowledge translation OR opinion leader)

Additional search terms from emerging themes during phase two run January 2016, search alerts scanned to February 2016

(dementia AND (pain) AND (hospital OR acute care OR secondary care))

(dementia AND (behaviour* OR BPSD) AND (hospital OR acute care OR secondary care))

Databases:

Cochrane Library (incl. CENTRAL, CDSR, DARE, HTA) (244), CINAHL (610), PubMed (4253), NHS Evidence (819) and Scopus (410)

*Study screening and data extraction*

Search results were downloaded into EndNote bibliographic software and duplicates deleted. One author (MH) screened titles and abstracts identified by the electronic search and applied the selection criteria to potentially relevant papers. Full texts of potentially relevant manuscripts were screened for relevance (whether the study has contributed to specific propositions relevant to the theory building) and rigour (whether they were of sufficient quality to provide credible evidence to help refine specific components of the proposition) [30, 31]. Appraisal of the contributions and reliability of evidence from papers continued throughout the synthesis through discussion with the other authors.

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Data were extracted by one author (MH) using a bespoke data extraction form organised to establish contributions and challenges to the theories, and strengths and weaknesses of the studies. Study characteristics such as design, setting, participants and sample size were also recorded [31]. The data extraction form was piloted by MH and shared with the team for comments and modifications [supplementary file 3]. To reduce the potential for bias during data extraction, a sample of the papers and their completed data extraction forms (6/28) were shared with FB and CG to appraise the extraction process and identified data. Information about the role and work of the change agent, the resources provided by the interventions, the contextual features of the settings (e.g. workforce, knowledge of dementia), explicit and implicit theories for how interventions were anticipated to work, and patient and carer outcomes were extracted. Coded data from all the papers and the relevant contribution to theory development were further refined after discussion with FB and CG, and challenges to interpretations were discussed to test their credibility. Evidence from the studies were first mapped to capture the complete range of possibilities of how different approaches and interventions triggered different responses from patients, family, and staff. After discussion amongst the authors, data were organised into tables to reflect the theoretical propositions they addressed (supplementary file 4) and to assist comparison of data across studies.

*Phase 3: Analysis and Synthesis*

Data synthesis was led by MH, with emerging findings discussed with the team (CG and FB), and the research network monitors (RP, JW, PM). Deliberations assisted the refinement of propositions, ensuring that emerging theories were plausible and clear. Discussions of papers included: the key characteristics of members of staff who support the implementation and uptake of interventions, resources, and new ways of working with people living with dementia (change agents); resources from interventions and how they were thought to influence staff reasoning; the impact of context; and possible undesired outcomes (such as stigmatising practises and broad application of strategies at the expense of individual needs). The focus was on understanding how patient outcomes were achieved through the actions of staff and what had supported staff to behave in particular ways. Recurring patterns in context and outcome (demi-regularities) detectible across studies were explained by explicit or implicit mechanisms. This led to the development of context-mechanism-outcome configurations designed to explain what it is about an intervention that works, for whom, and in what circumstances. The configurations were used to refine components of the initial theoretical propositions against the evidence.

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Box 2: Glossary of realist terms

Context: refers to factors, such as social or organisational influences, that may or may not be directly related to the intervention. For example staff profession and their role in the care of patients with dementia, or the way an organisation prioritised, and communicated commitments to dementia care.

Mechanism: includes the resource the intervention provides (such as training, assessments of pain, or access to biographical information about the patient) and the reasoning of the subjects, in this case the reasoning of staff (such as recognising the benefit of working differently) [38].

Outcome: The intended (or unintended) result. Patient outcomes of interest included; patient wellbeing, medication use (specifically analgesic and anti-psychotic, access to assessments, evidence of inclusion in care decisions, reduced distress, adverse incidents (such as falls or hospital acquired infection), length of stay, reduction in the onset of behaviours that challenge, maintenance of functions (such as activities of daily living).

Demi-regularity: a semi-predictable pattern of outcomes. For example, the provision of meaningful activities for patients with dementia will reduce their boredom and distress in hospital, leading to a reduction in the onset of behaviours that are challenging for staff.

Context-mechanism-outcome configuration: Specifies the relationship between the features (context, mechanism and outcome). It is the unit of analysis which is supports synthesis across studies to build and refine the programme theory.

## FINDINGS

### Phase 1

Evidence from 15 stakeholders was combined with literature on interventions aimed at improving health care for people living with dementia (22 papers) to generate three initial propositions for developing dementia friendly hospital environments. Interventions described in the literature can be seen in table 1.

Table 1: Papers included in Phase 1

| Intervention | Papers |
|---|---|
| Schemes to identify people with dementia admitted to the ward: e.g. a butterfly symbol above patient's bed to help identify people who have dementia linked to a training programme and the collection of biographical history from the family carer | [39] |
| Dementia Champion - Healthcare staff (mainly nursing staff) are trained to champion dementia care issues, providing support to peers | [27, 40-44] |
| Dementia Specialist Nurse - Senior Nurse working across the hospital as an expert in dementia to advise staff on treatment and care practices, and liaise with community services. | [45, 46] |
| Staff training and education - Training in dementia awareness and dementia care. | [9, 10, 28] |
| Liaison psychiatry / mental health teams - Specialist teams working across the hospital to advise staff on treatment and care and the treatment of delirium. | [47, 48] |
| Environmental adaptions - Changes to clinical areas including signage, new furniture, and improved flooring and lighting. | [15, 49] |
| Specialist Units for people living with dementia– include physical adaptions and specialist staff to treat the medical and psychological needs of people living with dementia | [50-54] |
| Use of Person Centred Care - model of care that prioritises the needs of the person. | [55] |

A key contextual factor to emerge from Phase 1 related to the role of change agents, although there were competing accounts of how a change agent might work and the responses they might trigger in staff. There appeared to be three distinct roles for change agents' activities that could lead to improved outcomes, these were;

- To support staff awareness and learning,
- To possess the authority to institute and sustain changes,
- To be a resource for staff as a clinical expert.

Change agent characteristics (e.g. supportive peer facilitator, organisational authority, clinical expertise) were considered to differently influence how staff engaged with interventions, and this, in turn, would impact on patient outcomes (table 2).

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Table 2: Initial theoretical propositions developed from phase 1

| Dementia friendly interventions in hospitals improve outcomes for people living with dementia and their carers if… | Evidence from stakeholders and preliminary scoping and supporting references |
|---|---|
| … a change agent supports staff to reframe their understanding of dementia and respond appropriately to people living with dementia through learning and resources which address patient needs in an individual way. **Then** staff will have increased awareness of dementia and the impact dementia has on a person, and build confidence in their ability to recognise and address distress. | Emphasis on training and education that improve staff confidence in working with people living with dementia. Breaking down negative assumptions and supporting staff to see the person rather than the diagnosis. Use of resources to get to know the person.<br><br>References: [9, 10, 28, 39-42, 44, 55-57]<br><br>Stakeholders (SK01, SK02, SK03, SK04, SK05, SK06, SK07, SK09, SK10, SK11, SK12, SK13, SK14)<br>Example quote: "we're starting to do some training with our staff as well just to try and help everyone to know how to approach and how to feel empathy towards these patients who have dementia." (SK12) |
| … a change agent with organisational and clinical authority communicates the priorities for dementia care and addresses staff concerns around managing risk and workplace disruption in person-centred ways. Staff are supported by training and resources that improve the involvement in decision-making and safety of people living with dementia, **then** staff will understand they have the permission and encouragement to adapt practices in ways that are beneficial for people living with dementia. | Strategic planning, prioritising good dementia care, providing resources that support staff to work in new ways, changes to systems and processes<br><br>References: [15, 42, 49-55]<br><br>Stakeholders (SK05, SK06, SK07, SK08, SK10, SK11, SK14, SK15)<br>Example quote: "…however good people's ideas are, if they don't have some kind of sign-off at a fairly senior level then they're not really going to have it 'cos they'll never be a |

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| | |
|---|---|
| | priority and because there are so many targets to be met in general, unless there's some kind of strategy or policy in writing I don't think it can change much really." (SK08) |
| … a change agent with clinical expertise in dementia and dementia care supports staff with assessments and care planning **then** staff will identify and resolve the care needs of people living with dementia. | Assessments of cognition, mental health, and psychosocial needs. Role modelling good dementia care. Supporting staff to perform care in a person-centred way, direct care planning and address complex issues such as decisions of best interest, access to mental and social care information.<br><br>References: [45, 47, 48, 50-52, 58]<br><br>Stakeholders (SK04, SK09, SK11, SK14, SK15)<br>Example quote: "we had mental health nurses came to work with us and they had a really important part in role-modelling how it looked, how to approach things." (SK14) |

**Phase 2**

Evidence from 28 papers, 12 of which had been identified and included in phase one of the review (supplementary file 5), led to the development of six context-mechanism-outcome configurations (CMOs) that explored the components of the three theoretical propositions developed in phase one (an overview of the selection process can be seen in Figure 1). These configurations are interconnected, representing key elements from the theories and how they relate to other factors (table 3). The CMOs and supporting evidence are discussed below.

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Table 3: Context-mechanism-outcome configurations and supporting evidence

| Brief title | Full Context-mechanism-outcome configuration | References |
|---|---|---|
| Supporting staff to reframe their understanding and how they respond to behaviours that challenge | Staff who are supported to understand and interpret behaviours that challenge as communication of an unmet need (context), through training, resources and support from experts in dementia care (mechanism resource) will recognise the importance of identifying the cause of the behaviour (mechanism reasoning) and respond appropriately to meet the person's individual needs (outcome). | [10, 15, 39, 40, 42, 45, 50, 52-55, 59-70] |
| The role of experiential learning and creating empathy to encourage reflection | Access to training (context) which promotes experiential learning and empathy towards people living with dementia (mechanism resource) will encourage reflection that prompts awareness how current working practices are deficient and instil a sense of responsibility to work well with people living with dementia (mechanism reasoning), leading to the adoption of care practices that consider the difficulties a person with dementia faces (outcome). | [10, 39, 40, 59, 62-64] |
| Clinical experts who support staff and have the authority to endorse priorities for care | Clinical experts who have the authority to define priorities and standards for dementia care endorsed by the organisation (context), provide support for staff to develop skills in dementia care (mechanism resource), staff will have confidence in expertise and the support they receive (mechanism reasoning) to adapt working practices (outcome) | [40, 42, 45, 48, 50, 53-55, 59, 61-64, 69-71] |
| Staff who have flexibility to provide | Staff with flexibility in their role and working environment (context), will use | [50, 55, 61, 62, 69] |

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| | | |
|---|---|---|
| care at an appropriate time | their professional judgement (mechanism reasoning) to provide care and treatment to a person in a timely manner (outcome), and will support patients in a person-centred way that is responsive to their needs (outcome). | |
| Staff with responsibility to focus on psychosocial needs | The provision of activities and therapies for people living with dementia that supports their interests and abilities (context) by staff with a role to address psychological, emotional and social issues (mechanism resource) are responsible (mechanism reasoning) for maintaining functional and cognitive abilities, (outcome), and provide other healthcare staff with time to prioritise physical and medical needs (outcome). | [10, 50, 51, 54, 55, 62, 64, 65, 68, 70, 72] |
| Building staff confidence to provide person-centred risk management | Staff who understand the procedures and expectations for care that address risk in a person-centred way (context), and are confident that they are supported by organisation (mechanism reasoning) will address risk proportionately (outcome). | [10, 15, 39, 50, 51, 53, 54, 64, 66-68, 70, 71] |

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*CMO 1. Supporting staff to reframe their understanding and how they respond to behaviours that challenge*

Studies frequently reported that where staff understood behaviour that challenged as communication of an unmet need, they were more likely to investigate the underlying cause rather than attempting to control and restrict the behaviour [15, 40, 42, 53, 60, 66, 70]. By addressing the unmet need, staff reduced patient distress [50, 55, 59, 62, 63, 65, 70] and maintained independence, for example by supporting mobility and toileting needs [39, 54, 64, 69]. Inappropriate and negative staff responses arose from lack of understanding and misinterpretation of behaviours that challenge, for example, interpreting the patient as being deliberately difficult [52, 68].

Strategies employed to reframe staff understanding of behaviours included: training in dementia [10, 15, 55, 59, 62]; the use of biographical tools, completed in partnership with informal carers, [39, 40, 53, 67, 70]; assessments of cognition, pain, and psychological needs [50, 51, 54, 60]; and access to experts in dementia care [40, 42, 45, 50, 54, 70]. Common to these interventions were that they supported staff to consider potential causes of behaviours and provided strategies to address the unmet need, such as the development of individualised care plans [45, 67] and personalised strategies for reducing distress [39, 70]. Training to recognise behaviours as the expression of an unmet need [59, 61], and knowledge of a patient gained through continuity in their care [55, 61, 62] helped staff become aware that particular care practices were unsuitable and to adapt their work in a way that benefitted the individual. However, personalisation of practices appeared to occur in pockets of activity rather than as an ethos of care provision. Even when staff understood and were supported to work well with people living with dementia with behaviours that challenged, their ability and willingness to address psychological needs was limited. Conflicting work demands, staff fatigue, long shifts, and difficulty in identifying and resolving patient issues resulted in staff responding to behaviours by ignoring and disengaging from the patient [50, 65].

*CMO 2. The role of experiential learning and creating empathy to encourage reflection*

Staff training that improved awareness of the impact of dementia and which addressed negative concepts was found to be a prerequisite for supporting good dementia care. While the literature suggested training had a positive impact on knowledge and confidence for working with people living with dementia, more work is need to understand how this works in practice [10, 39, 40, 59].

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Training strategies which employed experiential learning techniques and cultivated empathy in staff for people living with dementia prompted reflection on current practices. Evidence suggested these training sessions produced 'lightbulb moments' for staff where they gained a sudden realisation of the problems faced by people living with dementia [40, 59, 64]. This appreciation for the importance to adapt care practices prompted staff to work in ways that would better support the patient, and improved staff satisfaction with their work [39, 72]. Additionally, one study reported how staff associated the portrayals of people living with dementia in training materials to their own relatives. This encouraged staff to see people living with dementia as individuals and motivated them to take responsibility to put their learning into practice [59].

The use of reflection and examples of good care practices in recognisable situations gave staff a framework for working well with people living with dementia and demonstrated the benefit to their own work [59, 64]. However, these practices were often referred to by staff as 'going the extra mile' or being additional to their workload rather than being an expectation of their role. Staff needed to be confident additional time spent with patients would not be viewed negatively by colleagues or impact on the requirements to manage the ward effectively, to support adaptions to care practices [59].

*CMO 3. Clinical experts who support staff and have the authority to endorse priorities for care*

Change agents influenced staff working practices through clinical expertise and organisational authority [40, 42, 45, 48, 50, 54, 62, 63, 70]. Experts in dementia care supported staff in the use of assessment tools and person-centred care planning [48, 54], role modelled appropriate behaviour and communication for working with people living with dementia [40, 50], and provided professional advice for complex situations, such as decisions around best interests [42, 45]. Access to experts in dementia care was suggested to reassure and encourage staff to provide good care for people living with dementia. However, there was limited evidence that new practices were adopted by staff and embedded into everyday practice directly through their contact with dementia experts. Instead, it appeared that the experts maintained responsibility for dementia care, either personally or by providing direction. The use of experts alone could potentially concentrate responsibility for dementia care in a small staff group rather than create a culture where all staff are responsible. Evidence from one paper [50] suggested that even when ward staff

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as a whole were better able to work with people living with dementia, they would defer issues unrelated to physical or medical health care to dementia experts.

Clinical experts with a level of organisational authority endorsed changes to care practices by communicating values and standards for care at ward level [54, 55, 59, 62, 71] and across the organisation [53, 59, 63]. They addressed staff apprehensions to adaptions to care practices that previously prioritised medical and physical needs, ward routines, task focused ways of working, and organisational expectations for the completion of documentation and risk reduction [68]. Our review found when change agents in authority communicated new expectations for standards of care and changes to procedures, they validated the priorities for care permitting staff to adapt practices accordingly [53, 54, 59, 71]. However, the impact of changes to staffs' work needed to be recognised and supported [50, 53, 54, 62, 69-71]. For example, studies reported staff had reduced capacity to work with previous levels of patient allocation [53, 62, 69], and changes to risk management strategies, such as encouraging mobility in a frail patient population at risk of falls, required staff training [54, 71].

*CMO 4. Staff who have flexibility to individualise care*

The ability of staff to organise their work around the needs of people living with dementia rather than being restricted to the ward routine was linked to the provision of person-centred care [50, 55, 61, 62, 65, 69]. Where staff could incorporate getting to know the person, or recognise and respond directly to expressions of distress and unmet needs, patient wellbeing reportedly improved, evidenced through observations of more positive mood [55, 61, 62, 65].

Flexibility in working practices was suggested to be a factor in improving functional outcomes for people living with dementia. One study [69] attributed gains in mobility after hip surgery to therapy staff using their professional judgement to recognise optimal times that a person living with dementia would engage with a psychotherapy session, rather than risk the session being rejected. Additional factors that supported therapy staff to work flexibly included training in dementia care, reduced patient lists, and treatment rooms located on the ward [73].

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*CMO 5. Staff with responsibility to focus on psychosocial needs*

Time constraints and staffing resources limited staff capacity to provide good dementia care. This was often addressed by employing staff with a specific role prioritising psychological, emotional and social needs through the use of cognitive and psychosocial assessments, therapeutic activities, supervising mealtimes, and managing risk [10, 50, 52, 54, 62, 65, 68]. The use of these staff and the activities they provided improved patient experience [62], assisted orientation to time and place [65], reduced distress [50, 62, 65], and reduced the onset of behaviours that challenged staff [50]. Studies reported how activities were sometimes deliberately scheduled to cover known times of high need within the patient population, such as during the afternoon when 'sun-downing' might occur [54] or when staffing levels were stretched, such as during mealtimes. For example, activities co-ordinators offered social dining opportunities where they could support conversations and prompt patients to eat [50, 62, 65, 70]. Although studies reported improved nutritional intake this was not formally evaluated.

Patients with more severe physical illness or cognitive impairment may not be able to participate in activities [50, 52] although it is possible they may have benefited indirectly as healthcare staff had more time to address their physical and medical needs. While this was referred to in two of the interviews, this was not explored in any of the papers.

Ward-wide staffing levels and skill mix impacted on staff ability to prioritise emotional, psychological and social needs [50, 62]. At times of staff shortages, ward management prioritised safety and managing risk over other non-medical needs [50, 62]. Risk management techniques, such as the use of 'specials' could be applied in a way that also addressed psychosocial needs. Two studies [50, 62] described how staff allocated to monitor patients at risk of falls engaged the patients in games, activities, and conversations. However, this was not always the case as staff assigned as 'specials' were often junior team members, had not received training in dementia care, and were unclear of the purpose of the role beyond monitoring the patient. This resulted in a lack of interaction with the patient and increased patient distress [68].

*CMO 6 Building staff confidence to provide person-centred risk management*

We found evidence that addressing risk in a way that supported a person's abilities, choices and independence improved mobility [54, 64], reduced adverse incidents [70], and improved

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patient and carer satisfaction [50, 53, 67]. Training, for example, on new skills and procedures for managing risk from change agents with clinical expertise and organisational authority, ensured staff understood the benefits to patients and had confidence to implement approved working practices [54, 67, 71]. Structural factors influenced the way risk was addressed. For example wards with locked door access meant patients could be monitored from a distance without restricting their movement around the ward [50, 53, 54, 66]; potentially leading to a reduction in behaviours that challenge as 'wandering' behaviours were no longer considered problematic.

In open wards, alternative methods were developed to easily identify patients considered at risk of leaving the ward, such as the use of wrist bands and different coloured hospital clothing, allowing staff to monitor them from a distance and intervene as necessary [10, 59, 64]. Identification methods were supported by staff training in the appropriate way to encourage a patient to return to their ward [10, 64].

**Refined programme theory**

From data in phase one we hypothesised that the existence of a change agent was important for improving hospital care for people living with dementia. However, work in phase two suggested that a reliance on single initiatives, such as a change agent, was insufficient to change staff behaviour. Additional contextual factors were also necessary in order for staff to make use of the resources interventions provided and apply them in practice with people living with dementia. The six context-mechanism-outcome configurations have been incorporated into a refined programme theory to suggest what needs to be in place to encourage best practice for dementia care in hospitals (figure 2).

Contextual factors identified to provide conducive conditions for the provision of dementia friendly health care were:

- Staff awareness that behaviours that challenge should be considered as an expression of a person's needs.
- Provision, such as activity, therapy, or mental health staff, to enable the psychosocial and physical needs of people living with dementia are addressed equally.
- Clarity in staff roles and responsibilities for the priorities for caring for people living with dementia.
- Endorsement from staff with organisational authority for changes to care practice.

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Staff reasoning, or mechanisms, thought to interact with the above contexts and leading to staff adopting dementia friendly practices were: that they believed the approach is feasible; valued work that previously was not valued or seen as too difficult; had confidence in expertise and support received; and had awareness of how typical care practices were deficient. These mechanisms lead staff to understand the individual care needs of patients with dementia and make adjustments to care that recognised these needs. This staff outcome could then in turn became an important new context that would lead to improved outcomes for patients with dementia, as changes would help reduce distress that might otherwise complicate treatment of their acute needs. However, limited evidence to robustly support this necessitates further testing of the theory.

## DISCUSSION

Our review demonstrates how consideration of different contextual components in hospitals, hospital staff, and patients was fundamental to an intervention leading to improved healthcare outcomes for people living with dementia. Developing an understanding in staff of the difficulties dementia presents for people with the condition helped them to recognise the need to approach care differently. Previous reviews of dementia care in hospital settings have identified training as an important strategy to improve staff knowledge of dementia and confidence to work well with people living with dementia, but have provided limited evidence for how this effects patient outcomes [29, 74, 75]. Findings from this review would suggest that training as a single strategy is not enough to influence staff to adapt the care they provide for people living with dementia. The culture of care within an organisation needs to support staff to provide good care for people living with dementia. This means organisations need to recognise the impact this has on staff workload and roles and the changes that are necessary to ensure care provision has more flexibility. Staff needed to have a clear understanding of the expectation for care standards, and be confident that these changes are accepted by colleagues and senior staff if they are to improve the way care is provided for people living with dementia. Managerial endorsement for staff to work flexibly within their role, utilising practices and resources that enable them to get to know the person, will help staff to recognise and address signs of distress and implement best practice in dementia care.

Turner, et al. [74] suggests that to achieve the type of culture where person-centred care is valued, training in dementia should be aimed at a managerial level. Findings from this review would support their opinion; included studies where change agents in senior positions

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understood dementia and the associated impact on patient experience and care of the patient were reportedly able to influence the culture of care [53-55, 59, 63, 70, 72]. They communicated their vision for good dementia care, addressed the organisation of processes within and between departments, provided resources that supported staffs' work, and considered the impact of changes to roles and responsibilities. However, even with this endorsement, there were still times, such as concerns for managing risk and resource shortages, where staff responsibilities were reorganised to prioritise physical over psychological wellbeing.

Limited time and resources, and a preoccupation with managing risk are commonly cited factors that impact on the ability of staff and organisations to sustain dementia friendly hospital environments [29, 68, 74, 76, 77]. Employing staff who have a responsibility for the psychosocial needs of the patient can potentially improve patient experience of care while also making time available for nursing and medical staff to focus on physical and medical care needs of the patient. However, it is essential that contextual factors, such as staff awareness in dementia and dementia care, and staff clarification of their role and responsibilities are addressed before staffing resources are implemented into the setting. Moyle, et al. [68] demonstrated how the use of 'specials' without training in dementia care, a clear understanding of their role, and a prioritisation of risk management over addressing psychosocial needs resulted in poor outcomes for patients, such as increased agitation and reduced autonomy. A review on special observation [78] underlined the importance of clarity in the purpose of the role and adequately trained staff to optimise the role's therapeutic potential. Where responsibilities for care are assigned solely by the patient's symptoms this can lead to a narrow reactive approach to dementia care. Staff will still need to work as a team, rather than creating new tasks to focus on.

The initial aim of the review was to develop, test and refine a programme theory for how dementia friendly interventions influence outcomes for people living with dementia during hospital admissions. However, testing the theory was problematic as evidence was limited, much was descriptive, there were few evaluations of interventions and approaches, and limited descriptions of setting and component parts of the interventions which impacted on the development of CMO configurations. Moreover, most studies included in the review reported little information around patient characteristics (e.g. type and severity of dementia) which meant we were unable to establish how the characteristics of people living with dementia interacted with the components of the interventions to influence outcomes.

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Available evidence clustered around the training for staff and organisational support for changes to care practices. There was less evidence for how the introduction of staff providing activity and therapy for people living with dementia impacted on the practices of other staff. This review does, however, provide a programme theory that can be used as the basis for future evaluations. Our review also highlights the importance of focusing on patient related outcomes. It was clear from the initial interviews that whilst there was a shared understanding of the importance of dementia friendly care, less attention has been paid to how different approaches enhanced patient outcomes. By focusing on outcomes as the basis for inclusion, this review addresses a knowledge gap about how different resources and approaches for dementia friendly healthcare are effective for patients.

## CONCLUSION

The programme theory that has emerged from this review has the potential to improve how interventions to support dementia friendly care in hospitals are designed and evaluated. The review highlights what needs to be in place to maximise the impact of training and the key characteristics for staff acting as change agents to influence colleagues to practice good dementia care. Specifically, the elements of interventions need to be relevant to provide ward staff with the awareness, authority, and resources to provide personalised care with support from staff with the relevant expertise. Educational interventions should focus on how staff can identify with the experience of being a patient living with dementia, combined with opportunities for staff to share their experiences of addressing challenges linked with the impact of dementia related behaviours on ward routines and priorities. This review provides a timely contribution and challenges the assumption that dementia awareness initiatives in acute care settings alone are sufficient to improve patient care.

## CONTRIBUTORS

MH led the design and prepared the review as part of her PhD (University of Hertfordshire, Hertfordshire, UK) and led manuscript preparation. FB and CG wrote the original funding application, supervised the review development, and critically reviewed manuscript drafts. All authors contributed to the debate and interpretation of data, read, and approved the final manuscript.

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## AVAILABILITY OF DATA AND MATERIAL

All evidence cited in this review is available in the public domain. Data from the stakeholder interviews are not available to protect individuals' anonymity.


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## DISCLAIMER

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the paper.

## COMPETING INTERESTS

The authors declare that they have no competing interests.

## ETHICS APPROVAL

Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

## CONSENT FOR PUBLICATION

Participants in stakeholder interviews consented to participation and the use of anonymised interview excerpts.


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## REFERENCES


1. Alzheimer's Society. Fix Dementia Care: Hospitals. London: Alzheimer's Society, 2016.
2. Alzheimer's Society. Counting the cost: Caring for people with dementia on hospital wards: Alzheimer's Society London, 2009.
3. Poblador-Plou BC-L, Amaia; Marta-Moreno, Javier; Hancco-Saavedra, Jorge; Sicras-Mainar, Antoni; Soljak, Michael; Prados-Torres, Alexandra. Comorbidity of dementia: a cross-sectional study of primary care older patients. *BMC psychiatry* 2014;**14**(1):84
4. Bunn FB, Ann-Marie; Goodman, Claire; Rait, Greta; Norton, Sam; Robinson, Louise; Schoeman, Johan; Brayne, Carol. Comorbidity and dementia: a scoping review of the literature. *BMC medicine* 2014;**12**(1):192
5. Royal College of Psychiatrists. Report of the national audit of dementia care in general hospitals 2011: Healthcare Improvement Quality Partnership, 2013.
6. Bunn F, Dickinson A, Simpson C, et al. Preventing falls among older people with mental health problems: a systematic review. *BMC nursing* 2014;**13**(1):4
7. Orsitto G, Fulvio F, Tria D, Turi V, Venezia A, Manca C. Nutritional status in hospitalized elderly patients with mild cognitive impairment. *Clinical Nutrition* 2009;**28**(1):100-02
8. Bail K, Goss J, Draper B, Berry H, Karmel R, Gibson D. The cost of hospital-acquired complications for older people with and without dementia; a retrospective cohort study. *BMC health services research* 2015;**15**(1):91
9. Elvish RB, Simon; Cawley, Rosanne; Harney, Kathryn; Graham, Pat; Pilling, Mark; Gregory, Julie; Roach, Pamela; Fossey, Jane; Keady, John. 'Getting to Know Me': the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & mental health* 2014;**18**(4):481-88
10. Galvin JEK, Barbara; Al-Hammadi, Noor; Germino, Jessica; Murphy-White, Maggie; McGillick, Janis. "Dementia-friendly hospitals: care not crisis" An educational program designed to improve the care of the hospitalized patient with dementia. *Alzheimer disease and associated disorders* 2010;**24**(4):372
11. Bunn F, Goodman C, Brayne C, et al. Comorbidity and dementia: improving healthcare for people with dementia. www. nets.nihr. ac. uk/projects/hsdr/11101707. NIHR, HS & DR, 2012.
12. White N, Leurent B, Lord K, Scott S, Jones L, Sampson EL. The management of behavioural and psychological symptoms of dementia in the acute general medical hospital: a longitudinal cohort study. *International Journal of Geriatric Psychiatry* 2016
13. Benbow SMJ, David. Dementia: stigma and its effects. *Neurodegenerative Disease Management* 2012;**2**(2):165-72
14. Swaffer K. Dementia: Stigma, Language, and Dementia-friendly. *Dementia* 2014;**13**(6):709-16 doi: 10.1177/1471301214548143published Online First: Epub Date]|.
15. Waller S, Masterson A. Designing dementia-friendly hospital environments. *Future Hospital Journal* 2015;**2**(1):63-68
16. Department of Health. Living Well with Dementia: a national dementia strategy. In: Health Do, ed. London, 2009.
17. Department of Health. Prime Minister's challenge on dementia 2020. In: Health Do, ed. London, 2015.
18. Health Education England. Dementia: Improving dementia care through effective basic training and continuous professional and vocational development. Secondary Dementia: Improving dementia care through effective basic training and continuous professional and vocational development 2016. https://www.hee.nhs.uk/our-work/hospitals-primary-community-care/mental-health-learning-disability/mental-health/dementia.
19. World Health Organization. Global age-friendly cities: A guide: World Health Organization, 2007.


For peer review only

20. Crampton J, Dean, J., Eley, R., AESOP Consortium. Creating a dementia-friendly York: Joseph Rowntree Foundation York, 2012.
21. Mitchell L, Burton E, Raman S. Dementia-friendly cities: Designing intelligible neighbourhoods for life. *Journal of Urban Design* 2004;**9**(1):89-101 doi: 10.1080/1357480042000187721published Online First: Epub Date]|.
22. Mitchell L, Burton E. Designing dementia-friendly neighbourhoods: helping people with dementia to get out and about. *Journal of Integrated Care* 2010;**18**(6):11-18
23. https://www.dementiafriends.org.uk/. Dementia Friends. Secondary Dementia Friends.
24. Joseph Rowntree Foundation. Developing a national user movement for people with dementia - learning from the Dementia Engagement and Empowerment Project (DEEP). 2015
25. Royal College of Nursing. Dementia: Commitment to the care of people with dementia in hospital settings. London, 2013.
26. Department of Health. Prime Minister's challenge on dementia: Delivering major improvements in dementia care and research by 2015. In: Health Do, ed. London, 2012.
27. Mayrhofer AG, C.; Holman, C. Establishing a community of practice for dementia champions (innovative practice). *Dementia (London, England)* 2014 doi: 10.1177/1471301214542534published Online First: Epub Date]|.
28. Mayrhofer A, Goodman C, Sharpe R, Dye H. Dementia Education in Hertfordshire and Bedfordshire: An organisational audit commissioned by Health Education East of England. Centre for Research in Primary and Community Care (CRIPACC), University of Hertfordshire. Hatfield: University of Hertfordshire, 2014.
29. Dewing JD, Saskia. What is the current state of care for older people with dementia in general hospitals? A literature review. *Dementia* 2014:1471301213520172
30. Pawson R. Evidence-based policy: A realist perspective: Sage publications, 2006.
31. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC medicine* 2013;**11**(1):21
32. Pawson and Tilley. Realistic evaluation: Sage, 1997.
33. Handley M, Bunn F, Goodman C. Interventions that support the creation of dementia friendly environments in health care: protocol for a realist review. *Systematic reviews* 2015;**4**(1):1
34. Spencer; Ra. Qualitative data analysis for applied policy research. *The qualitative researcher's companion* 2002:305-29
35. Kitwood T, Bredin K. Evaluating dementia care the DCM method: Bradford, England: Bradford Dementia Research Group, Bradford University, 1997.
36. Wong G, Greenhalgh T, Pawson R. Internet-based medical education: a realist review of what works, for whom and in what circumstances. *BMC medical education* 2010;**10**(1):12
37. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review–a new method of systematic review designed for complex policy interventions. *Journal of health services research & policy* 2005;**10**(suppl 1):21-34
38. Dalkin SM, Greenhalgh J, Jones D, Cunningham B, Lhussier M. What's in a mechanism? Development of a key concept in realist evaluation. *Implementation Science* 2015;**10**(1):49
39. Williams R. Hospital programme for dementia-specific care: Using detailed observations of patients' experiences, Barbara Hodkinson developed the Butterfly Scheme to identify people with memory impairment and improve their care. She tells Ruth Williams how it works. *Nursing older people* 2011;**23**(7):14-17
40. Banks PW, A.; Henderson, J.; Sharp, B.; Brown, M.; Oliver, J.; Marland, G. Enriching the care of patients with dementia in acute settings? The Dementia Champions Programme in Scotland. *Dementia (London, England)* 2014;**13**(6):717-36 doi: 10.1177/1471301213485084published Online First: Epub Date]|.
41. Crabtree J, Mack J. Developing champions to enhance the care of people with dementia in general hospitals. *Nursing times* 2010;**106**(48):13-14

For peer review only

42. Ellison S, Watt G, Christie I. Evaluating the impact of the Alzheimer Scotland Dementia Nurse Consultants/Specialists & Dementia Champions in bringing about improvements to dementia care in acute general hospitals. 2014
43. Waugh AM, G.; Henderson, J.; Robertson, J.; Wilson, A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-9 doi: 10.7748/ns2011.04.25.32.44.c8452published Online First: Epub Date]|.
44. Wilkinson I, Coates A, Merrick S, Lee C. Junior doctor dementia champions in a district general hospital (innovative practice). *Dementia (London, England)* 2015 doi: 10.1177/1471301215584083published Online First: Epub Date]|.
45. Elliot R, Adams J. The creation of a Dementia Nurse Specialist role in an acute general hospital. *Journal of psychiatric and mental health nursing* 2011;**18**(7):648-52 doi: 10.1111/j.1365-2850.2011.01771.xpublished Online First: Epub Date]|.
46. Griffiths P, Bridges J, Sheldon H, Thompson R. The role of the dementia specialist nurse in acute care: a scoping review. *Journal of clinical nursing* 2014
47. Holmes J, Montaňa C, Powell G, et al. Liaison Mental Health Services for Older People: A Literature review, service mapping and in-depth evaluation of service models. *Produced for the National Institute for Health Research Service Delivery and Organisation programme* 2010
48. Baldwin R, Pratt H, Goring H, Marriott A, Roberts C. Does a nurse-led mental health liaison service for older people reduce psychiatric morbidity in acute general medical wards? A randomised controlled trial. *Age and ageing* 2004;**33**(5):472-78
49. Waller S. Redesigning wards to support people with dementia in hospital: Sarah Waller describes a programme that is bringing staff and patients together to create more welcoming and inspiring therapeutic environments. *Nursing older people* 2012;**24**(2):16-21
50. Goldberg S, Whittamore KH, Pollock K, Harwood RH, Gladman JR. Caring for cognitively impaired older patients in the general hospital: a qualitative analysis of similarities and differences between a specialist Medical and Mental Health Unit and standard care wards. *Int J Nurs Stud* 2014;**51**(10):1332-43 doi: 10.1016/j.ijnurstu.2014.02.002published Online First: Epub Date]|.
51. Goldberg S, Bradshaw, Lucy E; Kearney, Fiona C; Russell, Catherine; Whittamore, Kathy H; Foster, Pippa ER; Mamza, Jil; Gladman, John RF; Jones, Rob G; Lewis, Sarah A. Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial). *BMJ (Clinical research ed.)* 2013;**347**
52. Spencer K, Foster, P., Whittamore, K. H., Goldberg, S. E., Harwood, R. H. Delivering dementia care differently--evaluating the differences and similarities between a specialist medical and mental health unit and standard acute care wards: a qualitative study of family carers' perceptions of quality of care. *BMJ open* 2013;**3**(12):e004198 doi: 10.1136/bmjopen-2013-004198published Online First: Epub Date]|.
53. Nichols JN, Heller KS. Windows to the heart: Creating an acute care dementia unit. *Journal of palliative medicine* 2002;**5**(1):181-92
54. Zieschang T, Dutzi I, Müller E, et al. Improving care for patients with dementia hospitalized for acute somatic illness in a specialized care unit: a feasibility study. *International Psychogeriatrics* 2010;**22**(01):139-46
55. Scerri A, Innes A, Scerri C. Discovering what works well: exploring quality dementia care in hospital wards using an appreciative inquiry approach. *Journal of clinical nursing* 2015
56. Waugh A, Marland G, Henderson J, Robertson J, Wilson A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-49

For peer review only

57. Mayrhofer A, Goodman C, Holman C. Establishing a community of practice for dementia champions (innovative practice). *Dementia* 2015;**14** doi: 10.1177/1471301214542534published Online First: Epub Date]|.
58. Griffiths A, Knight A, Harwood R, Gladman JR. Preparation to care for confused older patients in general hospitals: a study of UK health professionals. *Age and ageing* 2013:aft171
59. Baillie L. An Evaluation of Barbara's Story: Final Report. London: Guy's and St Thomas' NHS Foundation Trust, London South Bank University, 2015.
60. Dowding D, Lichtner V, Allcock N, et al. Using sense-making theory to aid understanding of the recognition, assessment and management of pain in patients with dementia in acute hospital settings. *International Journal of Nursing Studies* 2016;**53**:152-62
61. Schneider J, Scales K, Bailey S, Lloyd J. Challenging care: the role and experience of health care assistants in dementia wards. *National Institute for Health Research Service Delivery and Organisation programme. Available online at http://panicoa. org. uk/sites/assets/challenging_care. pdf [Accessed August]* 2010
62. Bray J, Evans S, Bruce M, et al. Improving activity and engagement for patients with dementia. *Nursing older people* 2015;**27**(8):22
63. Brooker DM, Sarah; Evans, Simon; Carter, Christine; Bruce, Mary; Thompson, Rachel. RCN Development Programme: Transforming Dementia Care in Hospitals Evaluation Report. 2014
64. Duffin C. Raising awareness to support people with dementia in hospital: A film produced to train staff at one trust has had such a positive effect that it is to be used nationwide. Christian Duffin reports on this and other measures to improve care. *Nursing older people* 2013;**25**(5):14-17
65. Edvardsson D, Sandman PO, Rasmussen B. Forecasting the ward climate: a study from a dementia care unit. *Journal of clinical nursing* 2012;**21**(7-8):1136-114
66. Gonski PN, Moon I. Outcomes of a behavioral unit in an acute aged care service. *Archives of gerontology and geriatrics* 2012;**55**(1):60-65
67. Luxford K, Axam A, Hasnip F, et al. Improving clinician–carer communication for safer hospital care: a study of the 'TOP 5'strategy in patients with dementia. *International Journal for Quality in Health Care* 2015:mzv026
68. Moyle W, Borbasi S, Wallis M, Olorenshaw R, Gracia N. Acute care management of older people with dementia: a qualitative perspective. *Journal of clinical nursing* 2011;**20**(3-4):420-28
69. Rösler A, von Renteln-Kruse W, Mühlhan C, Frilling B. Treatment of dementia patients with fracture of the proximal femur in a specialized geriatric care unit compared to conventional geriatric care. *Zeitschrift für Gerontologie und Geriatrie* 2012;**45**(5):400-03
70. Upton. An evaluation of quality and cost effectiveness of a newly defined suite of care interventions for patients with dementia and their carers in the acute hospital setting developed by The Royal Wolverhampton Hospitals NHS Trust REPORT PHASE 2 – Volume 1: University of Worcester, 2012.
71. Enns E, Rhemtulla R, Ewa V, Fruetel K, Holroyd-Leduc JM. A controlled quality improvement trial to reduce the use of physical restraints in older hospitalized adults. *Journal of the American Geriatrics Society* 2014;**62**(3):541-45 doi: 10.1111/jgs.12710published Online First: Epub Date]|.
72. Harwood RH PD, King N, Edwards G, Hammond S, Howe L, et al. . Development of a Specialist Medical and Mental Health Unit for Older People in an Acute General Hospital. MedicalCrises in Older People Discussion Paper Series. Issue 5, November 2010., 2010.
73. von Renteln-Kruse W, Neumann L, Klugmann B, et al. Geriatric Patients With Cognitive Impairment: Patient Characteristics and Treatment Results on a Specialized Ward. *Deutsches Ärzteblatt International* 2015;**112**(7):103
74. Turner A, Eccles FJ, Elvish R, Simpson J, Keady J. The experience of caring for patients with dementia within a general hospital setting: a meta-synthesis of the qualitative literature. *Aging & mental health* 2015:1-11

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75. Digby R, Lee S, Williams A. Interviewing people with dementia in hospital: recommendations for researchers. *Journal of clinical nursing* 2016
76. Digby R, Lee S, Williams A. The experience of people with dementia and nurses in hospital: an integrative review. *Journal of clinical nursing* 2016
77. Borbasi S, Jones J, Lockwood C, Emden C. Health Professionals' Perspectives of Providing Care to People with Dementia in the Acute Setting: Toward Better Practice. *Geriatric Nursing* 2006;**27**(5):300-08 doi: 10.1016/j.gerinurse.2006.08.013published Online First: Epub Date]|.
78. Dewing J. Special observation and older persons with dementia/delirium: a disappointing literature review. *International journal of older people nursing* 2013;**8**(1):19-28

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Figure legends

Figure 1: Flow diagram of searches and evidence retrieval

Figure 2: Refined programme theory: CMO configurations for best practice for care of people living with dementia admitted to hospital

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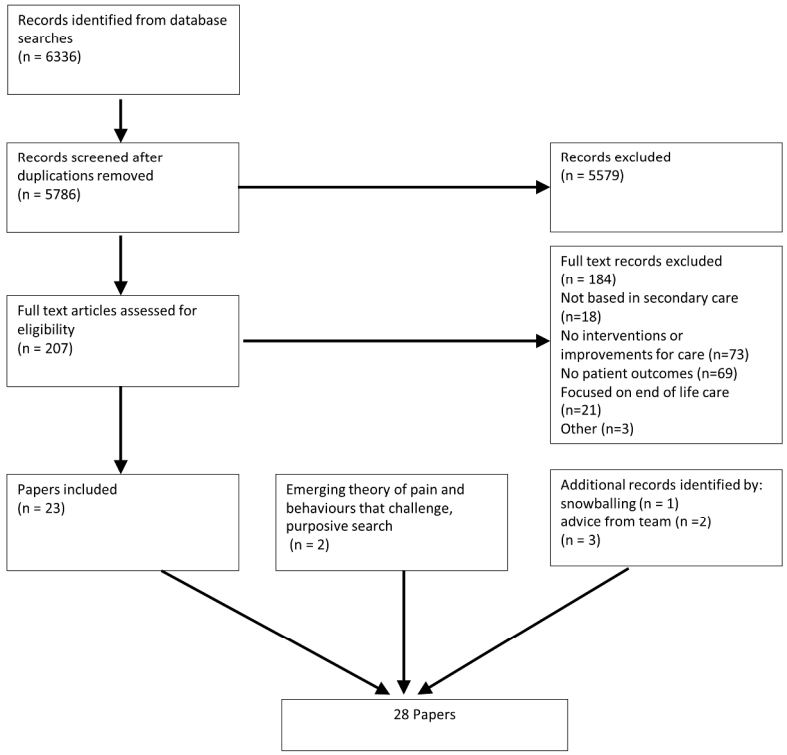


Figure 1: Flow diagram of searches and evidence retrieval

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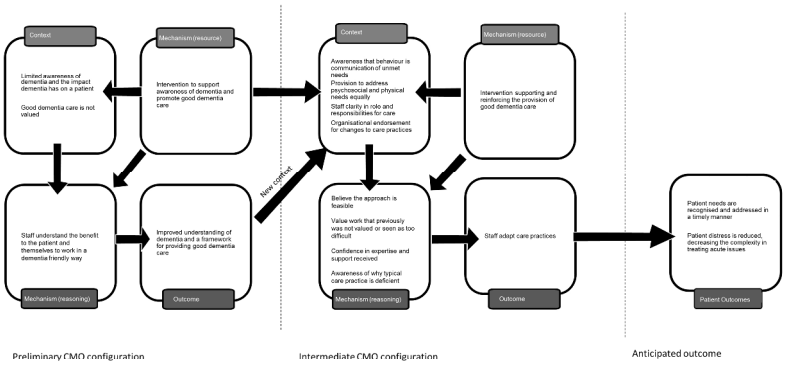


Figure 2: Refined programme theory: CMO configurations for best practice for care of people living with dementia admitted to hospital

Figure 2: Refined programme theory: CMO configurations for best practice for care of people living with dementia admitted to hospital

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# RAMESES publication standards: realist syntheses

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## Abstract

**Background:** There is growing interest in realist synthesis as an alternative systematic review method. This approach offers the potential to expand the knowledge base in policy-relevant areas - for example, by explaining the success, failure or mixed fortunes of complex interventions. No previous publication standards exist for reporting realist syntheses. This standard was developed as part of the RAMESES (Realist And MEta-narrative Evidence Syntheses: Evolving Standards) project. The project's aim is to produce preliminary publication standards for realist systematic reviews.

**Methods:** We (a) collated and summarized existing literature on the principles of good practice in realist syntheses; (b) considered the extent to which these principles had been followed by published syntheses, thereby identifying how rigor may be lost and how existing methods could be improved; (c) used a three-round online Delphi method with an interdisciplinary panel of national and international experts in evidence synthesis, realist research, policy and/or publishing to produce and iteratively refine a draft set of methodological steps and publication standards; (d) provided real-time support to ongoing realist syntheses and the open-access RAMESES online discussion list so as to capture problems and questions as they arose; and (e) synthesized expert input, evidence syntheses and real-time problem analysis into a definitive set of standards.

**Results:** We identified 35 published realist syntheses, provided real-time support to 9 on-going syntheses and captured questions raised in the RAMESES discussion list. Through analysis and discussion within the project team, we summarized the published literature and common questions and challenges into briefing materials for the Delphi panel, comprising 37 members. Within three rounds this panel had reached consensus on 19 key publication standards, with an overall response rate of 91%.

**Conclusion:** This project used multiple sources to develop and draw together evidence and expertise in realist synthesis. For each item we have included an explanation for why it is important and guidance on how it might be reported. Realist synthesis is a relatively new method for evidence synthesis and as experience and methodological developments occur, we anticipate that these standards will evolve to reflect further methodological developments. We hope that these standards will act as a resource that will contribute to improving the reporting of realist syntheses.

To encourage dissemination of the RAMESES publication standards, this article is co-published in the Journal of Advanced Nursing and is freely accessible on Wiley Online Library (http://www.wileyonlinelibrary.com/journal/jan).

Please see related article http://www.biomedcentral.com/1741-7015/11/20 and http://www.biomedcentral.com/1741-7015/11/22

**Keywords:** realist synthesis, realist review, publication standards

## Background

Academics and policymakers are increasingly interested in 'policy-friendly' approaches to evidence synthesis. Such approaches seek to illuminate issues and understand contextual influences on whether, why and how interventions might work [1,2]. A number of different approaches have been used to try to achieve this goal. At present there is lack of clarity on which methods are best suited for which questions or problems and this has been the subject of debate [3-6] and further research [7]. Realist synthesis is a theory-driven approach that is becoming increasingly popular.

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### What is a realist synthesis?

In this section we briefly describe the realist synthesis method. The realist research question is often summarized as "What works for whom under what circumstances, how and why?" Realist inquiry is based on a realist philosophy of science and considers the interaction between context, mechanism and outcome. From a realist perspective, intervention X is not thought of as having effect size Y with confidence interval Z. Rather, intervention X (for example, a program introduced by policymakers who seek to create a particular outcome) alters context (for example, by making new resources available), which then triggers mechanism(s), which produce both intended and unintended outcomes. Intervention X may work well in one context but poorly or not at all in another context.

Realist inquiry seeks to unpack the context - mechanism - outcome relationship, thereby explaining examples of success, failure and various eventualities in between. Theoretical explanations of this kind are referred to as "middle-range theories" (that is, ones which "...involve abstraction... but [are] close enough to observed data to be incorporated in propositions that permit empirical testing" [8].

The basis of realist inquiry is a realist philosophy, whose key tenets are as follows:

1. There is a [social] reality that cannot be measured directly (because it is processed through our brains, language, culture and so on), but can be known indirectly.

Realism thus sits, broadly speaking, between positivism ('there is a real world which we can apprehend directly through observation') and constructivism ('given that all we can know has been interpreted through human senses and the human brain, we cannot know for sure what the nature of reality is').

2. Social programs (including complex interventions) may change the macro social context (for example, by introducing legislation). They may also change the resources or opportunities available to participants and, in that sense, change the meso- or micro-level context for those participants.

3. To understand the relationship between context and outcome, realism uses the concept of mechanisms, one definition of which is "...underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest" [9].

In common with other theory-driven review methods, the realist approach offers the potential for insights that go beyond the narrowly experimental paradigm of the randomized controlled trial [10-12]. It can do so in relation to complex, complicated or simpler interventions (for example, even a simple intervention, such as a drug, is prescribed, dispensed and taken - or not - in a particular social, cultural and economic context).

"Realist synthesis" was first described by Ray Pawson in 2002 [13], updated in an ESRC (Economic and Social Research Council) commissioned monograph in 2004 [14], published as a book in 2006 [1] and summarizsed in a short methods paper in 2005 [15]. Since this paper is deliberately focused on publication standards, we strongly recommend that those unfamiliar with the realist approach consult these or other relevant methodological sources.

A realist synthesis (or realist review - these terms are synonymous) applies realist philosophy to the synthesis of findings from primary studies that have a bearing on a single research question or set of questions. Methodologically, reviewers may begin by eliciting from the literature the main ideas that went into the making of a class of interventions (the program theory). This program theory sets out how and why a class of intervention is thought to 'work' to generate the outcome(s) of interest. The pertinence and effectiveness of each constituent idea is then tested using relevant evidence (qualitative, quantitative, comparative, administrative and so on) from the primary literature on that class of programs. In this testing, the ideas within a program theory are re-cast and conceptualized in realist terms.

For each idea, reviewers seek out the contextual (C) influences that are hypothesized to have triggered the relevant mechanism(s) (M) to generate the outcome(s) (O) of interest. Synthesis consists of comparing 'how the programme was supposed to operate' to the 'empirical evidence on the actuality in different situations' - all along C-M-O lines. Analytic purchase comes from the ability to describe and understand the many contingencies that affect the likelihood of such interventions generating their intended outcomes. This in turn provides guidance about what policy makers or practitioners might put in place to change the context or provide resources in such a way as to most likely trigger the right mechanism(s) to produce the desired outcome.

### Why are publication standards needed?

Publication standards are common (and, increasingly, expected) - in health services research - see, for example, CONSORT for randomized controlled trials [16], AGREE for clinical guidelines [17], PRISMA for Cochrane-style systematic reviews [18] and SQUIRE for quality improvement studies [19]. For realist syntheses, publication standards are particularly important as this method is relatively new and concerns have been expressed about the rigor with which some realist reviews have been carried out and reported [20]. Publication standards are needed to ensure that users of reviews are provided with relevant and necessary information to enable them to assess the quality and rigor of a review.

In our experience, there is considerable confusion among researchers, journal editors, peer reviewers and

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funders about what counts as a high quality realist review and what, conversely, counts as a flawed review. Even though experts still differ on detailed conceptual methodological issues, the increasing popularity of this method prompted a study to develop baseline standards from which, we anticipate, further developments in theory and methodology of this approach will occur.

## Aim

The aim of this paper is to produce preliminary publication standards for realist syntheses.

## Methods

The methods we used to develop these reporting standards have already been published [20]. In brief, we purposively recruited an international group of experts to our online Delphi panel. Aiming to achieve maximum variety in the relevant sectors, disciplines and expert perspectives represented, we sought panel members working in realist research, evidence synthesis, publication, reviewer training and health policy. Prior to the start of our Delphi panel, with input from an expert informaticist (JB), we collated and summarized existing literature on the principles of good practice in realist synthesis, created a database of such published syntheses, and built relationships with teams who were undertaking ongoing syntheses. Through discussion within the project team, we considered the extent to which the principles had been followed by published and in-progress reviews, thereby identifying how rigor may be lost and how existing methods could be improved.

Our analysis of existing realist syntheses formed the basis of the briefing materials for the first round of the Delphi panel. In addition, we drew on our collective experience in training and supporting realist syntheses teams and an email discussion list on realist and meta-narrative methodology [21] to further inform the contents of our briefing document. Both the research team and panel members contributed draft items for the publication standards, and these were refined using the online Delphi process as previously described [20]. We ran the Delphi panels between September 2011 and March 2012.

### Description of panel and items

In all, we recruited 37 individuals from 27 organizations in 6 countries. These comprised: researchers in public or population health researchers (8); evidence synthesis (6); health services research (8); international development (2); education (2); and also research methodologists (6), publishing (1), nursing (2) and policy and decision making (2). In round 1, 22 Delphi panel members provided suggestions of items that should be included in the publication standards. In rounds 2 and 3 our panel members were asked to rate each potential item for relevance and clarity. The response rates across all items for rounds 2 and 3 were 93% and 89%, respectively. Consensus was reached within three rounds on both the content and wording of 19 items within the publication standards. Table 1 provides an overview of these items.

### Scope of the publication standards

These publication standards are intended to help researchers, authors, journal editors, and policy and decision makers to know and understand what should be reported in the write-up of a realist synthesis. They are not intended to provide detailed guidance on how to conduct such a synthesis; for this, we direct interested readers to summary articles [15,22] or various publications on methods [1,11,14,23]. This publication standard applies only to realist syntheses. A list of publication guidelines for other review methods can be found on the EQUATOR Network's website [24], but at present none of these relate specifically to realist syntheses. As part of the RAMESES project we are also developing quality standards and training materials for realist syntheses, which will be submitted as a separate publication. Publication standards for meta-narrative reviews (also covered in the RAMESES project) have been addressed in a separate article.

### How to use these publication standards

The layout of this document has drawn on previous methodological publications and, in particular, on the 'Explanations and Elaborations' document of the PRISMA statement [18]. Each item is followed by an example drawn from published reviews and a rationale for its inclusion. The purpose of the example text is to illustrate how an item might be reported in a write up. However, potentially relevant contextual information may have been omitted, so it may be necessary to consult the original paper from which the example text was drawn. The standards set out what might be expected for each item, but authors will still need to exercise judgement about how much information to include. The purpose of the details reported should be to ensure that the description and explanation provided is coherent and plausible, both against the guidance set out within an item and for the overall purpose of the realist synthesis.

While this publication standard is modeled on the PRISMA statement, the items within are not identical. This publication standard, developed to apply only to realist syntheses, has some overlap with the PRISMA statement. Items 1 to 3, 15, 16 and 19 in this statement broadly match the purpose of items 1 to 3, 24, 25 and 27 in the PRISMA statement. For items 4 to 14, while there is some overlap in purpose with some PRISMA statement items, different or additional reporting is needed due to the nature of realist syntheses. Other items (5, 12, 13, 15, 16, 19

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**Table 1 List of items to be included when reporting a realist synthesis**

| | | |
|---|---|---|
| **TITLE** | | |
| 1 | | In the title, identify the document as a realist synthesis or review |
| ABSTRACT | | |
| 2 | | While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice. |
| INTRODUCTION | | |
| 3 | Rationale for review | Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area. |
| 4 | Objectives and focus of review | State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review. |
| METHODS | | |
| 5 | Changes in the review process | Any changes made to the review process that was initially planned should be briefly described and justified. |
| 6 | Rationale for using realist synthesis | Explain why realist synthesis was considered the most appropriate method to use. |
| 7 | Scoping the literature | Describe and justify the initial process of exploratory scoping of the literature. |
| 8 | Searching processes | While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected. |
| 9 | Selection and appraisal of documents | Explain how judgements were made about including and excluding data from documents, and justify these. |
| 10 | Data extraction | Describe and explain which data or information were extracted from the included documents and justify this selection. |
| 11 | Analysis and synthesis processes | Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process. |
| RESULTS | | |
| 12 | Document flow diagram | Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example templates (which are likely to need modification to suit the data) that are provided. |
| 13 | Document characteristics | Provide information on the characteristics of the documents included in the review. |
| 14 | Main findings | Present the key findings with a specific focus on theory building and testing. |
| DISCUSSION | | |
| 15 | Summary of findings | Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s). |
| 16 | Strengths, limitations and future research directions | Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged.<br>The limitations identified may point to areas where further work is needed. |
| 17 | Comparison with existing literature | Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic. |
| 18 | Conclusion and recommendations | List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice. |
| 19 | Funding | Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers. |

and 23) in the PRIMSA statement have no equivalent in the RAMESES publication standards for realist reviews.

The order in which items are reported may vary. Realist syntheses are not 'linear' reviews. Some of the processes that are listed may legitimately take place in parallel or have to be revisited at a later date as a review progresses. As a general rule, if a recommended item is excluded from the write-up of a realist synthesis, a justification should be provided.

### The RAMESES publication standards for realist syntheses

#### *Item 1: Title*

In the title, identify the document as a realist synthesis or review.

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**Example**

"Human resource management interventions to improve health workers' performance in low and middle income countries: a realist review." [25]

**Explanation**

Our background searching has shown that some realist reviews are not flagged as such in the title and may also be inconsistently indexed and, hence, are more difficult to locate during searching. The terms 'realist synthesis' and 'realist review' are both in widespread use. We asked our Delphi panel if they had a preferred term - 'realist synthesis' or 'review'. No consensus was reached by our Delphi panel on whether 'review' or 'synthesis' should be the preferred term, and there seemed no good reason to impose one or other term.

***Item 2: Abstract***

While acknowledging that requirements and house style may differ between journals, abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.

**Example**

***"Background***

Legislation is one of the most powerful weapons for improving population health and is often used by policy and decision makers. Little research exists to guide them as to whether legislation is feasible and/or will succeed. We aimed to produce a coherent and transferable evidence based framework of threats to legislative interventions to assist the decision making process and to test this through the 'case study' of legislation to ban smoking in cars carrying children.

***Methods***

We conceptualised legislative interventions as complex social interventions and so used the realist synthesis method to systematically review the literature for evidence. 99 articles were found through searches on five electronic databases (MEDLINE, HMIC, EMBASE, PsychINFO, Social Policy and Practice) and iterative purposive searching. Our initial searches sought any studies that contained information on smoking in vehicles carrying children. Throughout the review we continued where needed to search for additional studies of any type that would conceptually contribute to helping build and/or test our framework.

***Results***

Our framework identified a series of transferable threats to public health legislation. When applied to smoking bans in vehicles; problem misidentification, public support; opposition; and enforcement issues were particularly prominent threats. Our framework enabled us to understand and explain the nature of each threat and to infer the most likely outcome if such legislation were to be proposed in a jurisdiction where no such ban existed. Specifically, the micro-environment of a vehicle can contain highly hazardous levels of second hand smoke. Public support for such legislation is high amongst smokers and non-smokers and their underlying motivations were very similar - wanting to practice the Millian principle of protecting children from harm. Evidence indicated that the tobacco industry was not likely to oppose legislation and arguments that such a law would be 'unenforceable' were unfounded.

***Conclusion***

It is possible to develop a coherent and transferable evidence based framework of the ideas and assumptions behind the threats to legislative intervention that may assist policy and decision makers to analyse and judge if legislation is feasible and/or likely to succeed." [26]

**Explanation**

Apart from the title, an abstract is the only source of information accessible to searchers unless the full paper is obtained. The information in it must allow reviewers and/or users to decide if the review is relevant to their needs.

**Introduction section**

The following items should be reported in the introduction section.

***Item 3: Rationale for review***

Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.

**Example**

"A number of reviews on the subject have tried to examine evidence to improve the operationalization of interventions by CHWs [community health workers], including for child health. Lehmann *et al.* (Reference x1) and Lewin *et al.* (Reference x1) have reviewed evidence on CHW interventions in LMIC [low-middle income countries] and Haines *et al.* (Reference x1) have particularly so for child health. Lewin *et al.* (Reference x1) found lay health workers to be effective in specific areas in child health, when compared to usual care. Haines *et al.* (Reference x1) highlight the contextual nature of CHW's performance. Both caution that CHW interventions are not the panacea for all that ails the health systems in LMIC and that large scale CHW programmes should be initiated with great caution. Both raise questions about the applicability of findings to different settings and about the conditions under which CHW interventions should be implemented." [27]

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**Explanation**

As with all research, a background section explaining what is already known and what the researchers considered to be the 'knowledge gaps' is a helpful orientation.

***Item 4: Objectives and focus of review***

State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.

**Example**

"The overriding question for the review was: Does moving from high-poverty neighborhoods to lower-poverty neighborhoods improve health? More specifically: What were the key health outcomes? Who experienced these outcomes? What appeared to be the mechanisms and associated context leading to the outcomes? As the review proceeded, it became clear that one of the only relatively consistent and statistically significant positive health outcomes was an improvement in mental health for adult women, children and adolescent girls. In this paper a review of mental health outcomes of MTO [Moving To Opportunity] is presented, along with some insights about the mechanisms and contexts through which the intervention appears to have impacted mental health." [28]

**Explanation**

A realist research question contains some or all of the elements of 'What works, how, why, for whom, to what extent and in what circumstances, in what respect and over what duration?' and applies realist logic to address the question (see Item 11).

Because a realist synthesis may generate a large number of avenues that might be explored and explained, and because resources and timescale are invariably finite, the expectation is that the review must be 'contained' by progressively focusing both its breadth (how wide an area?) and depth (how much detail?). This important process may involve discussion and negotiation with, for example, content experts, funders and/or users. It is typical and legitimate for the synthesis' objectives, question and/or the breadth and depth of the review to evolve as the review progresses. How and why it evolved is usually worth reporting.

**Methods section**

The following items should be reported in the methods section.

***Item 5: Changes in the review process***

Any changes made to the review that was initially planned should be briefly described and justified.

**Example**

"As the review progressed we became aware of various data suitability limitations (see Discussion) and the emergence of two prominent demi-regularities prompted us to narrow our review focus to the two candidate theories discussed below." [29]

**Explanation**

A realist synthesis can (and, in general, should) evolve over the course of the review. For example, changes to the research question or its scope are likely to have an impact on many of the synthesis' subsequent processes. However, this does not mean the synthesis can meander uncontained. An accessible summary of what was originally planned (for example, as described in an initial protocol) and how and why this differed from what was done should be provided as this may assist interpretation.

***Item 6: Rationale for using realist synthesis***

Explain why realist synthesis was considered the most appropriate method to use.

**Example**

"Previous reviews sought to understand PR [participatory research] and provide practical recommendations (References x6) and to assess the value of PR to research goals, health status, and systems change (References x6). Nonetheless, the assessment of outcomes remains weak (Reference x4), partly because the methodologies used have generally failed to embrace the complexity of programs or address mechanisms of change (Reference x1). ...

To handle such complexity, we chose a realist approach (Reference x1) because it provides a rationale and tools for synthesizing complex, difficult-to-interpret evidence from community-based programs." [30]

**Explanation**

Realist synthesis is a theory-driven method that is firmly rooted in a realist philosophy of science. It places particular emphasis on understanding causation (in this case, understanding how programs and policies generate outcomes through human decisions) and how causal mechanisms are shaped and constrained by social context. This makes it particularly suitable for reviews of certain topics and questions - for example, complex social programs that involve human decisions and actions. It also makes realist synthesis *less* suitable than other review methods for certain topics and questions - for example, those which seek primarily to determine the average effect size of a simpler intervention administered in a single or limited range of conditions. In our analysis of 37 published realist syntheses, the most common limitation was inadequate engagement with realist explanatory principles and the implications these have, first, for understanding programs and how they work, and second, for cumulating evidence and explanation.

Some realist syntheses published to date have deliberately adapted the method as first described by Pawson.

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Sometimes, adaptations may be entirely justifiable, but at other times they may indicate a poor grasp of realist methodology. To enable judgement to be made on adaptations, the description and rationale for adaptations should be provided. Such information will allow criticism, debate and counter criticism among review teams and users on the suitability of such adaptations, and may well facilitate methodological development.

***Item 7: Scoping the literature***

Describe and justify the initial process of exploratory scoping of the literature.

**Example**

"To develop our framework on the threats to the programme theory of public health legislation we started out by conducting a rapid review of broad areas of public health legislation (covering everything from gun amnesties to food labelling) trying to uncover what had been the sticking points in legislation and how (if at all) they had been circumvented. This outline review led to the construction of a provisional framework for reviewing the family of legislative interventions (as described in Figure 1). .... . Beginning with this framework and through discussions (and with reference to other interested stakeholders) we focused on a subset of themes that seemed most relevant in respect to the intervention in question. In our case, we deliberately sought input from the NICE officer seconded to our project." [26]

**Explanation**

This step is used to build an understanding of the topic area. For example, this step may be used to identify provisional program theories, the names/titles of programs within scope and key authors in the area. Initial attempts to make sense of a topic area may involve informal 'browsing' of the literature and also consulting with experts and stakeholders.

***Item 8: Searching process***

While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.

**Example**

"...the literature search was iterative and ongoing throughout the project. An initial search was conducted of various academic databases, such as Academic Search Premier, Arts and Humanities Citation Index, Canadian Research Index, as well as through various search engines, such as Prowler, Novanet, Google and Google Scholar. Search terms included: Moving to Opportunity [MTO]; housing intervention; housing mobility; housing health effects; low-

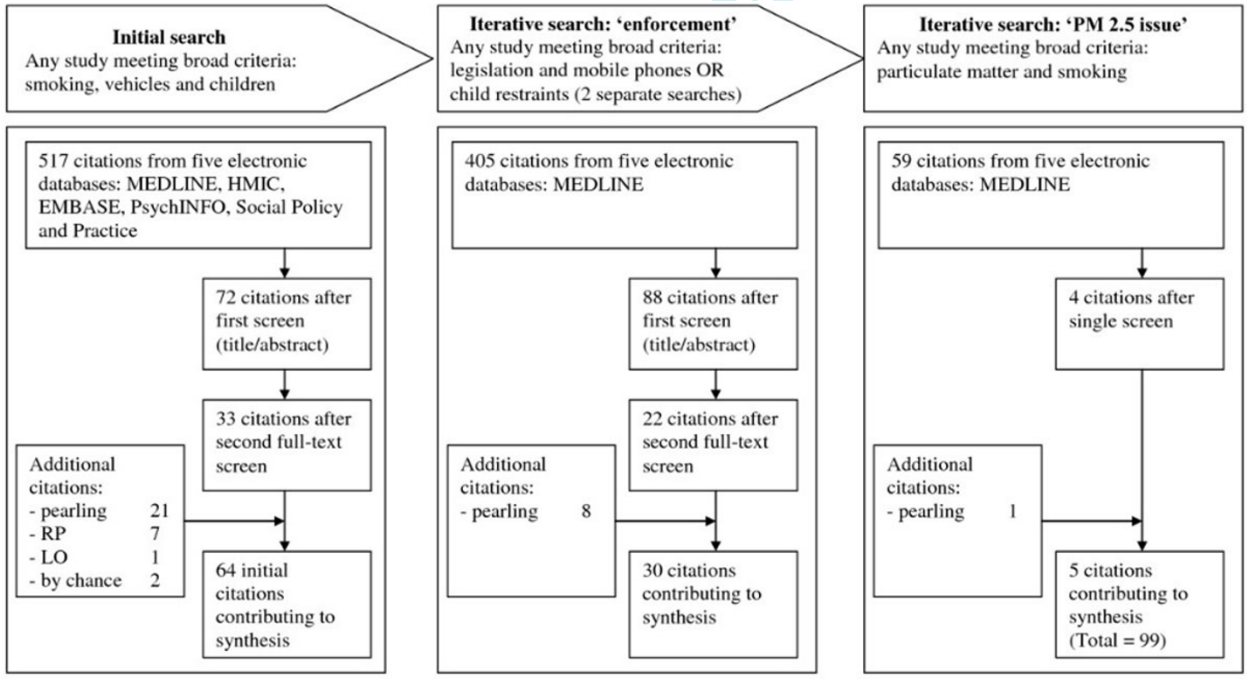


**Figure 1** Flow diagram illustrating search process and article disposition [26].

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poverty neighborhood/community; high-poverty neighborhood/community; neighborhood/community health; poverty neighborhood/community; poverty community effects; poverty housing; poverty health; and housing health. A "snowball" approach was used in which one reference led to others. Other evaluations were revealed through correspondence with Dr. Jeffrey Kling, one of the principal MTO researchers." [28]

**Explanation**

Searching should be guided by the objectives and focus of the synthesis, and revised iteratively in the light of emerging data. Data relevant to a realist synthesis may lie in a broad range of sources that may cross traditional disciplinary, program and sector boundaries. The search phase is thus likely to involve searching for different sorts of data, or studies from different domains, with which to test different aspects of any provisional theory.

Search methods using forward and backward citation tracking may be particularly valuable in finding the documents necessary to develop and then test provisional theories. Realist syntheses do not exclude sources solely on the basis of their study design; hence, 'methodological filters' (for example, to identify randomized controlled trials) may add little to the search and could potentially miss relevant papers.

Searching is likely to be iterative because, as the synthesis progresses, new or refined elements of theory may be required to explain particular findings, or to examine specific aspects of particular processes. As new elements of theory are included, searches for evidence to support, refute or refine those elements may be required. If undertaken, the process used for any such additional searches should be clearly documented. A single pre-defined search is unlikely to be sufficient and may suggest insufficient reflection on emerging findings.

Sufficient detail should be given to enable the reader to judge whether searching was likely to have located sources needed for theory building and/or testing.

***Item 9: Selection and appraisal of documents***

Explain how judgements were made about including and excluding data from documents, and justify these.

**Example**

"Three tools were developed (for identification, selection, and appraisal) in March, June, and October 2009, respectively. Modifications were made during each stage after piloting. Each stage processed a different type of data: citations in identification; full-text papers in selection; and sets of publications in appraisal.

...The identification tool consisted of three questions. This step funnelled the number of citations from 7,167 to 594.

The librarian (JH) retrieved the 594 full-text papers, which were read by two independent reviewers, using a selection tool initially comprised of six questions in June 2009, with an additional two questions added in October 2009. ...

Two hundred articles remained from 594 after filtering them through the selection tool. Due to the complexity of the dataset, we decided at this stage to further limit the scope of our review to community-based settings, and to participatory interventions. Our rationale was that: PR in all forms (community-based PR, organizational PR, action research) was too diverse to be assessed within one review; the complexity of PR benefits from community-based research provided a manageable set of studies; intervention research demonstrated more complexity of outcomes than non-intervention research, and would be best suited for analysis using realist review methods; and the pool of studies needed to be reduced to a manageable size for an in depth realist synthesis (analysis). Adding two questions reduced the pool to 83 studies.....

Contact with principal investigators of all full-text papers retained after selection was undertaken because descriptions of programs, methods and findings of PR interventions were found to be commonly described across a number of publications pertaining to the same intervention. It was thus necessary to confirm that we had complete sets of papers in order to fairly appraise projects according to the realist review approach. ... For each study, we then sent our list of papers to the corresponding author or PI, and asked them to confirm that we had the complete set, or to send us additional documents. ... Only those sets of studies in which the contacted researcher responded to our request were retained for appraisal.

.... The appraisal tool consisted of three questions. An additional 11 sets were eliminated after screening with the tool below, which left a total of 23 sets, comprising 276 documents that were retained for synthesis. See Appendix 4: ... for a complete breakdown of the number of cases retained at each stage." [30]

**Explanation**

Realist synthesis is not a technical process - that is, following a set protocol will not guarantee that a review will be robust. Rather, it requires a series of judgements about the relevance and robustness of particular data for the purposes of answering a specific question.

Within any document, there may be several pieces of data that serve different purposes, such as helping to build one theory, refining another theory and so on. Therefore, the selection (for inclusion or exclusion) and appraisal of the contribution of pieces of data within a document cannot be based on an overall assessment of study or

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document quality. An appraisal of the contribution of any section of data (within a document) should be made on two criteria:

- *Relevance* - whether it can contribute to theory building and/or testing; and
- *Rigor* - whether the method used to generate that particular piece of data is credible and trustworthy.

A wide range of documents can potentially contribute to a realist synthesis. For example, outcome and impact studies, qualitative interviews, ethnography, questionnaire surveys, mixed-method case studies, and close reading of policies, business plans, websites, project initiation documents and 'gray literature' write-ups of programs may all contribute in different ways of identifying and elucidating program theories. Because of this range and realist review's focus on relevance and rigor, it can initially be difficult to 'whittle down' the number of documents that are potentially eligible for inclusion in a review. This process can only occur as the data sources are analyzed in detail. Thus, in practice, the selection and appraisal stage may need to run in parallel with the analysis stage.

It is unlikely that authors will be able to provide an in-depth description of each decision involved, but the broad processes used to determine relevance and assess rigor (for example, using quality standards appropriate to particular kinds of research to appraise documents or sections of documents; discussion and/or debate within a review team of a document's findings; or consulting experts about technical aspects of methods or findings) should be described. While the description of the processes followed will not allow the reader to draw firm conclusions about judgements made, it will give an indication of the coherence, plausibility and appropriateness of the processes used to inform those judgements.

***Item 10: Data extraction***

Describe and explain which data or information were extracted from the included documents and justify this selection.

**Example**

"In order to identify key elements of importance to the success or failure of an intervention in a certain context using a realist perspective, information was gathered on the intervention, the context and the actual "working of the intervention" or the mechanisms. As we intended to discuss the strength of the evidence and the usefulness of the application of realist principles to already published studies, we developed a process of data analysis that was comprehensive and as objective and transparent as possible. Therefore, a data analysis matrix was developed by the team of authors (see Annex 2). During the development of this matrix, the team extensively discussed and defined terms (such as context, mechanisms and outcome) and evaluation levels (such as process, output and outcome)." [31]

**Explanation**

In a realist synthesis, data extraction assists analysis and synthesis. Reporting on what was extracted and why can add to the transparency of the synthesis process.

The extracted data may consist of descriptions (for example, of the detail of what was done in a program), findings (for example, cure rates, mortality) or explanations about how and why the program may have worked in particular contexts. Of particular interest to the realist reviewer are data that support the use of realist logic to answer the review's question(s) - for example, data on context, mechanisms and outcome configurations, demi-regularities, middle-range and/or program theories. Realist synthesis is used for a wide range of research questions, so it is impossible to be prescriptive about what data should be extracted. However, the link between the research question and the category of data extracted should be clear.

***Item 11: Analysis and synthesis processes***

Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.

**Example**

"Data synthesis was undertaken either by RP and/or GW and synthesis results were regularly shared and discussed within the review team to ensure validity and consistency in the inferences made. Specifically (where relevant), we attempted to identify prominent recurrent patterns of contexts and outcomes (demi-regularities) in the data and then sought to explain these through the means (mechanisms) by which they occurred. For example, we noted that in our included articles self-reported public support for a ban on smoking in vehicles carrying children was often found to be high amongst smokers. During data synthesis we would then aim to provide an explanation of this demi-regularity through the identification of mechanism(s). As we delved further into our included articles and beyond (through our aforementioned purposive searching) for an explanation, data emerged that smokers harboured within them the wish to want to protect children from harm and also regret at having started smoking. We interpreted these as (realist) mechanisms and, for the former, were able to find substantive (middle-range) theory in the form of the Millean principle [Reference x1] to explain its interaction with context to influence outcomes. When additional studies were sought to enable programme theory testing, data handling processes .... were repeated." [26]

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**Explanation**

In a realist synthesis, the analysis and synthesis processes occur iteratively and may be sequential or in parallel. At the center of any realist analysis is the application of a realist philosophical 'lens' to data. A realist analysis of data specifically seeks to analyze data using realist concepts. Specifically, realism adheres to a generative explanation for causation - that is, an outcome (O) of interest was generated by relevant mechanism(s) (M) being triggered in context (C). Within or across the included documents, recurrent patterns of outcomes (or demi-regularities) and their associated mechanisms and contexts (CMO configurations) are likely to occur.

During synthesis the goal is to make sense of the analyzed data using theory, at one of two levels. First, theory (or theories) may be sought, developed and/or refined to explain how it is that a program (or part of a program) achieves its outcomes (that is, the mechanism(s) operating within a program) and the contexts in which those mechanisms do and do not fire. This provides a realist program theory. Second, theory (or theories) may be sought, developed and/or refined to explain, at a somewhat more general level, the pattern of contexts, mechanisms and outcomes. A full realist analysis addresses both these levels and attempts to make sense of the relationship between these two levels. Syntheses which address only one level may also be considered realist syntheses assuming that they apply and demonstrate application of a realist philosophy of science. The level(s) of analysis chosen will depend on the review's focus. The theories used may have been developed and/or refined from the data and/or be refinement of existing substantive theory.

The key analytic process in realist review involves iterative testing and refinement of theoretically based explanations using empirical findings in data sources. Reviewers may draw on any appropriate analytic techniques to undertake this testing. Explanation and justification for the choice of techniques should be provided.

Ideally a description should be provided on how all the individuals involved in the review have been involved in the analysis and synthesis processes, and how these evolved as the review took shape.

**Results section**

The following items should be reported in the results section.

***Item 12: Document flow diagram***

Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example provided (which is likely to need modification to suit the data) in Figure 1.

**Example**

"See Figure 1: Flow diagram illustrating search process and article disposition." [26]

**Explanation**

A flow diagram provides an accessible summary of the sequence of steps and gives an indication of the volume of data included and excluded at each step.

***Item 13: Document characteristics***

Provide information on the characteristics of the documents included in the synthesis.

**Example**

"Additional File 1 summarises ..., the context, the intervention, the mechanisms triggered and the reported outcomes. Additional File 1 shows that in all the trials, more than one type of intervention was applied to improve CHWs [community health workers] performance. It also shows that the outcomes are reported not in terms of CHW performance, but rather in terms of the consequences of their performance on specific health outcomes." [27]

**Explanation**

A clear summary of the characteristics of included sources can add to the transparency of the synthesis and some characteristics may help readers judge the coherence and plausibility of inferences. Examples of possibly relevant characteristics of documents that may be worth reporting include, where applicable: full citation, country of origin, study design, summary of key main findings, use made of document in the synthesis and relationship of documents to each other (for example, there may be more than one document reporting on an intervention). While considering specific requirements of any particular publication, reviewers may wish to tabulate key characteristics.

***Item 14: Main findings***

Present the key findings with a specific focus on theory building and testing.

**Example**

"Using this theoretical concept, we hypothesized that equitable partnerships, with the stakeholders' participation throughout the project, succeed largely through synergy. Through the synthesis process using CMO configuring, we refined the theory by demonstrating that synergy is both an outcome and a context for partnership development - so that when synergy generated positive outcomes (e.g., enhanced trust or improved data collection), those outcomes generated new synergy. Expanding this logic, we demonstrated how partnership synergy created momentum over time, producing resilience in the face of obstacles as well as sustaining health-related goals, extending

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programs and infrastructure, and creating new and unexpected ideas and activities." [30]

**Explanation**

The defining feature of a realist synthesis is the nature of the theory(ies) it offers. Such a theory explains why a social program/intervention generates particular outcomes in particular contexts, in terms of one or more mechanisms - that is how the program's infrastructure and resources trigger particular decisions or behaviors in human participants. Program theories are usually 'middle-range' - that is, specific enough to generate propositions that can be tested about aspects of the program but sufficiently abstract to be applicable to other programs. Mechanisms are contingent: they are causal processes that have a tendency to occur in a particular set of conditions, but which do not always occur (because the circumstances have to be right for any particular mechanism to operate, and because many mechanisms can operate concurrently, sometimes cancelling each other out).

The validity of a review which is described as 'realist' and which talks about program theories or mechanisms but which expresses these as simple and linear relationships between variables should be questioned.

The findings of a realist synthesis consist largely of inferences about the links between context, mechanism and outcome and the theory(ies) that seek to account for these links. It is important that where inferences are made these are clearly articulated. Where possible, especially for key findings, it is important to include an explanation to show how these inferences were arrived at.

Transparency of the synthesis process can be demonstrated, for example, by including such things as a detailed worked example, verbatim quotes from primary sources, and (if appropriate) an exploration of disconfirming data (that is, findings which appeared to refute the program theory but which, on closer analysis, could be explained by other contextual influences).

When presenting inferences about context-mechanism-outcome configurations, reviewers should be clear about what they have categorized as context, what as mechanism and what as outcome. In a realist synthesis a mechanism involves the interaction between particular inputs (or resources) and human reasoning, which produces a particular outcome (or not).

More than one piece of data might be needed to support an inference. It is sometimes appropriate to build the argument for an inference as an unfolding narrative in which successive data sources increase the strength of the inference [32]. Provide enough details about each data item to identify its source and enable readers to make judgements about its relevance and rigor.

**Discussion section**

The following Items should be reported in the discussion section.

***Item 15: Summary of findings***

Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s).

**Example**

"This realist review of 249 primary studies has produced two key findings which are important, if somewhat unsurprising. First, Internet-based courses must engage their target group of learners to use the technology. This is likely to occur only if the technology is perceived as 'useful' (e.g.increases access to learning or saves time) and 'easy to use', though benefits in the former can outweigh challenges in the latter. Second, 'interactivity' is highly valued by learners. Learners wanted to be able to enter into a dialogue with the course tutor, fellow students and/or a virtual tutorial and obtain ongoing feedback on their understanding and performance." [29]

**Explanation**

In order to place the findings in the context of the wider literature and any specific policy need, it is necessary to summarize briefly what has been found. This section should be succinct and balanced, explaining the relevance of one or more key theories that emerged from the analysis and highlighting the strength of evidence for the main inferences. This should be done with careful attention to the needs of the main users of the synthesis.

***Item 16: Strengths, limitations and future research directions***

Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged.

The limitations identified may point to areas where further work is needed.

**Example**

"We explicitly chose to do a realist review of the RCTs [randomized controlled trials] to see what they could additionally yield. While the CHWs [community health workers] were an important component of the interventions being tested in the RCTs, none of the RCTs under review explicitly focused on performance of the CHW as an outcome. The RCTs under review offered a fair amount of information about the interventions, only some information about context - allowing us to formulate only generic hypotheses. ...

... Authors seldom described or discussed the mechanisms that explained their study outcomes. We realise that

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the RCT design, the exacting reporting requirements and word limits of journals, restrict authors from sharing all their operational experiences. In addition RCTs tend to report average effects and not differential effects of interventions, and less so of the context and rarely of the mechanisms triggered by their interactions. This makes the RCTs less useful for answering the questions regarding how interventions work. These generic hypotheses seem to be recurring in the literature, however they have not been explicitly tested across contexts." [27]

**Explanation**

Realist synthesis may be constrained by time and resources, by the skill mix and collective experience of the research team, by the scope of the review's questions or objectives and/or by anticipated or unanticipated challenges in the data. These should be made explicit so that readers can interpret the findings in the light of them. A common challenge in realist synthesis is that in order to focus the synthesis, some material is omitted at each successive stage. Some aspects of the topic area, therefore, end up being reviewed in detail and rich explanatory insights produced for these. Other aspects are neglected (relatively or absolutely). It is thus inevitable that in generating illumination, the synthesis will also cast shadows. These should be highlighted in the discussion so as to indicate areas where other syntheses might focus.

Strengths and/or limitations associated with any modifications made to the synthesis process should also be reported and justified.

***Item 17: Comparison with existing literature***

Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic.

**Example**

"We were unable to find any comparable attempt at providing an evidence-based-policy framework such as ours. However, we acknowledge that some sections of our framework may be found in sources we have not uncovered and also as tacit knowledge within the heads of seasoned practitioners (e.g. advocates or legislators). We do however hope that our attempts to develop and test it on our one 'case study' will make a primordial tool that will be useful to policy and decisions makers less well versed in the arena of public health legislation." [26]

**Explanation**

Comparing and contrasting the findings from a synthesis with the existing literature may help readers to put these into context. For example, this item might cover questions such as: How does this synthesis compare to other reviews (for example, were they theory-driven?); What does this synthesis add?; Which body of work in particular does it add to?; Has this synthesis reached the same or different conclusion to previous reviews?; and Has it answered a question previously identified as important in the field?

***Item 18: Conclusion and recommendations***

List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.

**Example**

"Our realist review was based on a housing intervention in the United States, but the results can potentially be applied to urban centers in other nations that implement housing interventions that involve moving families. When a family moves, the experience is likely to be different for each member of the household, and differences in mental health outcomes of moving may occur (Reference x1). All communities, rich or poor, and irrespective of geographic location, should be viewed as complex systems, and as composed of people with social relationships that influence the functioning and health of community members." [28]

**Explanation**

A clear line of reasoning is needed to link the findings (Results section) with the implications (Discussion and/or Conclusion). If the synthesis is small and preliminary, or if the coherence and plausibility of evidence behind the inferences is weak or moderate, statements about implications for practice and policy should be appropriately guarded.

If recommendations are given, these should take into account the focus of the synthesis and needs of the intended audience and be presented appropriately. The explanations in realist analysis are highly dependent on contextual influences. It follows that recommendations must be contingent (for example, only under certain contexts will a particular mechanism be triggered to generate the desired outcome) rather than statements that X should or should not be done.

***Item 19: Funding***

Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers.

**Example**

"We gratefully acknowledge a financial contribution from the Dutch Development Cooperation (DGIS)." [25]

**Explanation**

The source of funding for a synthesis and/or personal conflicts of interests may influence the research question, methods, data analysis and conclusions. No review is a 'view from nowhere', and readers will be better able to interpret the review if they know why it was done and for which sponsor.

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If a synthesis is published, the process for reporting funding and conflicts of interest as set out by the publication concerned should be followed.

## Discussion

We have developed these publication standards for realist synthesis (which we view as synonymous with realist review) by drawing together a range of sources - namely, existing published evidence, a Delphi panel and comment, discussion and feedback from a mailing list, training sessions and workshops. We hope these standards will lead to greater consistency and rigor of reporting and, thereby, make the outputs of realist synthesis more accessible, usable and helpful to different stakeholders.

This publication standard is not a detailed guide of how to undertake a realist synthesis. Other resources, both published (see Background) and in preparation, are better suited for this purpose. These standards have been developed as a guide to assist the quality of reporting of realist syntheses and the work of publishers, editors and reviewers. As part of the RAMESES project, we will be developing and disseminating both training materials and quality standards for realist synthesis [20].

Because realist synthesis is used for a broad range of topics and questions, and because it involves making judgements and inferences rather then checking against or following a technical checklist, it is impossible to be prescriptive about what exactly must be done in a review. The guiding principle is that transparency is important, as this will help readers to decide for themselves if the arguments for the judgements made were reasonable, both for the chosen topic and from a methodological perspective. We strongly encourage review authors to provide detail on what they have done and how - in particular with respect to the analytic processes used. These standards are intended to supplement rather than replace the exercise of judgement by editors, reviewers, readers and users of realist syntheses. We have tried to indicate in each item where judgement needs to be exercised.

The explanatory and theory-driven focus of realist syntheses means that detailed data may need to be reported in order to provide enough support for inferences and/or judgments made. While developing these publication standards, it became apparent that in some cases the word count limitations imposed by journals did not enable review teams to fully explain aspects of their synthesis - such as how judgments were made or inferences arrived at. Alternative ways of providing the necessary detail may need to be found, such as online appendices or additional files available from authors on request.

Previous efforts to develop publication standards have sometimes been criticized for being too 'ivory-tower' and failing to take account of real-world problems faced by reviewers. In an effort to redress this problem in the RAMESES project, we sought from the outset to engage not just senior academics but also junior and mid-career researchers, practitioners, policymakers and publishers in the development of the standards and to capture real-life challenges of ongoing realist syntheses as these emerged.

## Conclusions

We have developed these publication standards for realist syntheses by drawing on a range of sources. Our hope is that these standards will lead to greater consistency and rigor of reporting and make the outputs of realist syntheses more accessible, usable and helpful to different stakeholders. Realist synthesis is a relatively new approach to evidence synthesis and with increasing use and methodological development, changes are likely to be needed to any publication standards. We hope to continue capturing and improving these publication standards, through our email list [21] and wider links and discussions with researchers and those who commission, sponsor, publish and use realist syntheses.

### Abbreviations

ESRC: Economic and Social Research Council; RAMESES: Realist And MEta-narrative Evidence Syntheses: Evolving Standards).

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**Authors' contributions**

GWo carried out the literature review. JB searched the literature for realist syntheses. GWo, TG, GWe and RP analyzed the findings from the review and produced the materials for the Delphi panel. They also analyzed the results of the Delphi panel. GWo, TG, GWe and RP conceived of the study and participated in its design. GWo coordinated the study and ran the Delphi panel. All authors read and approved the final manuscript.

**Competing interests**

The authors declare that they have no competing interests. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR program, NIHR, NHS or the Department of Health.

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**References**

1. Pawson R: *Evidence-based Policy: A Realist Perspective* London: Sage; 2006.
2. Pearson M, Coomber R: **The challenge of external validity in policy-relevant systematic reviews: a case study from the field of substance misuse.** *Addiction* 2010, **105**:136-145.
3. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A: **Synthesising qualitative and quantitative evidence: a review of possible methods.** *J Health Serv Res Policy* 2005, **10**:45-53.
4. Barnett-Page E, Thomas J: **Methods for the synthesis of qualitative research: a critical review.** *BMC Med Res Methodol* 2009, **9**:59.
5. Pope P, Mays N, Popay J: *Synthesizing Qualitative and Quantitative Health Research: A Guide to Methods* Maidenhead, UK: Open University Press; 2007.
6. Gough D, Oliver S, Thomas J: *An Introduction to Systematic Reviews* London: Sage; 2012.
7. Kastner M, Tricco A, Soobiah C, Lillie E, Perrier L, Horsley T, Welch V, Cogo E, Antony J, Straus S: **What is the most appropriate knowledge synthesis method to conduct a review? Protocol for a scoping review.** *BMC Med Res Methodol* 2012, **12**:114.
8. Merton R: *On Theoretical Sociology. Five Essays, Old and New* New York: The Free Press; 1967.
9. Astbury B, Leeuw FL: **Unpacking black boxes: mechanisms and theory building in evaluation.** *Am J Eval* 2010, **31**:363-381.
10. Shepperd S, Lewin L, Straus S, Clarke M, Eccles M, Fitzpatrick R, Wong G, Sheikh A: **Can we systematically review studies that evaluate complex interventions?** *PLoS Med* 2009, **6**:e1000086.
11. Rycroft-Malone J, McCormack B, Hutchinson AM, DeCorby K, Bucknall TK, Kent B, Schultz A, Snelgrove-Clarke E, Stetler CB, Titler M, Wallin L, Wilson V: **Realist synthesis: illustrating the method for implementation research.** *Implement Sci* 2012, **7**:33.
12. Robert E, Ridde V, Marchal B, Fournier P: **Protocol: a realist review of user fee exemption policies for health services in Africa.** *BMJ Open* 2012, **2**: e000706.
13. Pawson R: **Evidence-based policy: the promise of 'realist synthesis'.** *Evaluation* 2002, **8**:340-358.
14. Pawson R, Greenhalgh T, Harvey G, Walshe K: *Realist Synthesis - an Introduction. ESRC Working Paper Series* London: Economic and Social Research Council; 2004.
15. Pawson R, Greenhalgh T, Harvey G, Walshe K: **Realist review–a new method of systematic review designed for complex policy interventions.** *J Health Serv Res Policy* 2005, **10(Suppl 1)**:21-34.
16. Moher D, Hopewell S, Schulz K, Montori V, Gotzsche P, Devereaux P, Elbourne D, Egger M, Altman D, for the CONSORT Group: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trial.** *BMJ* 2010, **340**:c869.
17. Brouwers M, Kho M, Browman G, Burgers J, Cluzeau F, Feder G, Fervers B, Graham I, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L, AGREE Next Steps Consortium: **AGREE II: advancing guideline development, reporting and evaluation in healthcare.** *Can Med Assoc J* 2010, **182**:E839-842.
18. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D: **The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration.** *BMJ* 2009, **339**: b2700.
19. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S, SQUIRE Development Group: **Publication guidelines for improvement studies in health care: evolution of the SQUIRE project.** *Ann Intern Med* 2008, **149**:670-676.
20. Greenhalgh T, Wong G, Westhorp G, Pawson R: **Protocol - realist and meta-narrative evidence synthesis: evolving standards (RAMESES).** *BMC Med Res Methodol* 2011, **11**:115.
21. RAMESES JISCM@il: [www.jiscmail.ac.uk/RAMESES].
22. Wong G, Greenhalgh T, Westhorp G, Pawson R: **Realist methods in medical education research: what are they and what can they contribute?** *Med Educ* 2012, **46**:89-96.
23. Wong G: **The internet in medical education: a worked example of a realist review.** In *Synthesising Qualitative Research: Choosing the Right Approach.* Edited by: Hannes K, Lockwood C. Chicester, UK: Wiley-Blackwell; 2011:.
24. EQUATOR Network: [http://www.equator-network.org/home/].
25. Dieleman M, Gerretsen B, van der Wilt GJ: **Human resource management interventions to improve health workers' performance in low and middle income countries: a realist review.** *Health Res Policy Syst* 2009, **7**:7.
26. Wong G, Pawson R, Owen L: **Policy guidance on threats to legislative interventions in public health: a realist synthesis.** *BMC Public Health* 2011, **11**:222.
27. Kane SS, Gerretsen B, Scherpbier R, Dal Poz M, Dieleman M: **A realist synthesis of randomised control trials involving use of community health workers for delivering child health interventions in low and middle income countries.** *BMC Health Serv Res* 2010, **10**:286.
28. Jackson L, Langille L, Lyons R, Hughes J, Martin D, Winstanley V: **Does moving from a high-poverty to lower-poverty neighborhood improve mental health? A realist review of 'Moving to Opportunity'.** *Health Place* 2009, **15**:961-970.
29. Wong G, Greenhalgh T, Pawson R: **Internet-based medical education: a realist review of what works, for whom and in what circumstances.** *BMC Med Educ* 2010, **10**:12.
30. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, Sirett E, Wong G, Cargo M, Herbert CP, Seifer SD, Green LW, Greenhalgh T: **Uncovering the benefits of participatory research: implications of a realist review for health research and practice.** *Milbank Q* 2012, **90**:311-346.
31. Dieleman M, Kane S, Zwanikken P, Gerretsen B: *Realist Review and Synthesis of Retention Studies for Health Workers in Rural and Remote Areas* Geneva, Switzerland: World Health Organization; 2011.
32. Pawson R, Wong G, Owen L: **Known knowns, known unknowns, unknown unknowns: the predicament of evidence-based policy.** *Am J Eval* 2011.

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**Supplementary file 2: RAMESES publication standards checklist**

| | | |
|---|---|---|
| 1 | Title identified as realist review | Yes |
| 2 | Abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice. | Yes |
| 3 | Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area. | yes |
| 4 | State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review. | yes |
| 5 | Any changes made to the review that was initially planned should be briefly described and justified. | Yes |
| 6 | Explain why realist synthesis was considered the most appropriate method to use. | Yes |
| 7 | Describe and justify the initial process of exploratory scoping of the literature. | Yes |
| 8 | state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected. | Yes |
| 9 | Explain how judgements were made about including and excluding data from documents, and justify these. | Yes |
| 10 | Describe and explain which data or information were extracted from the included documents and justify this selection. | Yes |
| 11 | Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process. | Yes |

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| 12 | Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). | Yes |
| 13 | Provide information on the characteristics of the documents included in the synthesis. | Yes |
| 14 | Present the key findings with a specific focus on theory building and testing. | Yes, although theory testing was limited due to limited evidence, this is discussed in the paper |
| 15 | Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s). | Yes |
| 16 | Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged. The limitations identified may point to areas where further work is needed. | Yes |
| 17 | Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic. | Yes |
| 18 | List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice. | Yes |
| 19 | Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers. | Yes |

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Supplementary file 3: Data extraction form

# Theory Areas

1. **If a change agent supports staff to understand how to interpret and respond to PLWD behaviour that uses PCC approaches, challenges poor practice by using experiential learning and patient centred resources and reflection, then staff will be more likely (mechanism confidence, awareness, prioritise) to engage and assess patient pain / distress and involve PLWD and carer in planning their care**

2. **If a change agent has organisational and clinical authority to introduce learning and credible resources that prioritise the identification and care of PLWD and addresses concerns around risk and workplace disruption within a PCC framework then staff will feel they have permission to do the right thing becoming less risk averse**

3. **If a change agent works as a clinical expert to identify and resolve the care needs of PLWD then staff will feel supported and be more willing to care for PLWD**

| ***Source**(ref):* | |
|---|---|
| **Author lens** | |
| **Country** | |
| **Type of study/paper** | |
| **Intervention** | |
| **Relevance:**<br>*Are the contents of a section of text within an included document referring to data that might be relevant to our mid-range theories? Which ones?* | |
| | |
| 2. Outcomes of interest<br>Are the outcomes of interest referred to in the paper? Which ones? | |
| 1) Patient and carer involvement in decision making<br>2) Length of hospital admission<br>3) Occurrence of adverse incidents (falls, nutrition, delirium)<br>4) Use of antipsychotic medication<br>5) Needs assessment<br>6) Patient and carer satisfaction<br>7) Other not specified | |
| **What are the characteristics of the change agent** | |
| | |
| **What are the characteristics of person centred care** | |
| | |
| **What is the change agent trying to do** | |
| | |

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| **What resources are in place to help them achieve their aims** |
| |
| **To what extent are their aims achieved, what is the evidence?** |
| |
| **In what context is the change agent working?** |
| |
| **3. Interpretation of meaning:**<br>*If it is relevant, do the contents of a section of text provide data that may be interpreted as being context, mechanism (resource/response) or outcome?* |
| |
| **4. Judgements about Context-Mechanism-Outcome-Configurations:**<br>*What is the Mechanism (resource)-Context-Mechanism (response)-Outcome Configuration (CMOC) (partial or complete) for the data?* |

| Resource/Intervention | Context | Mechanism | Outcome |
|---|---|---|---|
| | | | |

| |
|---|
| **5. Judgements about mid-range theory:**<br>• *How does this (full or partial) CMOC relate to the mid-range theory?*<br>• *Within this same document are there data which informs how the CMOC relates to the mid-range theory?*<br>• *If not, are these data in other documents? Which ones?*<br>• *In light of this CMOC and any supporting data, does the mid-range theory need to be changed?* |
| |
| **6. Rigour:**<br>• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the CMOC?*<br>• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the mid-range theory?* |
| |
| **7. Population** |
| |
| **Questions raised not captured elsewhere** |
| |
| **Notes** |
| |

Supplementary file 2

Evidence for theory area 1: To support staff awareness and learning

| Paper | Example Evidence | Key Points and emerging CMOs |
|---|---|---|
| Baillie (2015) [59] | "I think the Barbara's Story made me more aware of them so I go to help them where perhaps I may not necessarily have noticed them before. (Therapists1)" (p26)<br><br>"After seeing the video it makes those kinds of patients easier to speak with and it also reassures you, so for example in the video it talks about not taking them out of their own reality, and I think that just reassures people that you can distract them and not 'lie' to them and that's okay, and I think that's reassuring to people that don't know that much about dementia." (p46)<br><br>"Staff remembered Barbara being 'lost', 'confused', 'vulnerable', 'scared' and 'worried'. They engaged with her as a person who could be a family member… Some staff specifically related Barbara's Story to a family member, which personalised the film's story… There was also acknowledgement that any of us could find ourselves in a similar situation." (p24)<br><br>"Barbara's Story enabled staff to see her healthcare experience from her perspective and the behaviour shown in the film prompted staff to reflect on their own behaviour and that of colleagues." (p23)<br><br>"In most focus groups, staff discussed how their own interactions with patients and behaviour had changed since watching Barbara's Story, and they often referred to changes they had observed in other staff too. Areas discussed included: giving more time to patients, improved communication, giving more information, and assisting patients who are looking lost." (p25) | Raising awareness to recognise signs and symptoms of dementia<br><br>Training to improve confidence in working with people living with dementia<br><br>Reassurance from examples in training of how to work well with people living with dementia<br><br>Training that developed empathy helped staff relate to people living with dementia as family members<br><br>Shown experience from patient's viewpoint to understand how need to adapt care practices<br><br>Changes staff implemented after training; time for patients, better communication, information, recognising and acting upon distress and confusion. |

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| | Some participants considered that Barbara's Story had raised the profile of initiatives and other work that was already in place for people with dementia, further reinforcing and helping developments to embed in the Trust, such as dementia study days and dementia champions and use of the forget-me-not." (p29) | Training supporting and promoting the use of other resources. |
| | "Staff related how they listened to patients with a history of dementia, taking their physical symptoms more seriously, rather than attributing them to their dementia: 'we will now investigate it a little bit more [...] any physical symptoms we will take seriously' [rather than attributing it to their dementia or mental health condition (Nurse10). Similarly, in relation to behaviour, another nurse said:<br>I think it's really important for staff to remember not to play a part in that stigma and not to make excuses if they're upset or aggressive, not to put it down to their condition, sometimes they are just genuinely wanting something or upset. (Nurses8)" (p51) | Staff reported changes to practices following training. Understanding behaviours as communication of other needs rather than symptoms of dementia. |
| | "Those who had used This is me were great advocates for the tool and the difference it made in practice:<br>I saw it once in practice and I thought to myself, this is the best thing that anyone has ever done because it just made the care you gave so personalised and I remember the patient and it said in the notes, loves Coronation Street and EastEnders. So at 7.30pm I'd go and put on Coronation Street, just because I knew about it. (Nurses4)<br>… It's nice to know a bit more about them, what they like and don't like, even if it's just down to how they like their tea or they don't like tea. (Nurses6)" p53 | Use of biographical tool to understand the preferences and routines of the patient. |
| | In one focus group, an example of the benefits of This is me was explained:<br>She [patient with dementia] was in for less than three days, got home, she wasn't a delayed discharge but my point had been if This Is me hadn't been filled in and she was distressed and constantly calling, they'd have given her [medication], shut her up, then she'd have been over-sedated, she wouldn't have been eating and drinking, her delirium would have been worse. (Nurses4) | How not knowing about the patient leads to distressed behaviours that might have adverse results such as inappropriate medication, poor nutrition and hydration, and increased severity of delirium. |

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| Banks (2014) [40] | "[this is me] By having this document we have reduced the amount of medication the patient receives in hospital. Staff are much more likely to look into why the patient is behaving this way rather than get them prescribed medication. This in turn has reduced the number of falls during the day, therefore reducing the number of fractures and increased stays in hospital. P727<br><br>The first change we made was to stop separating the patient with dementia from the relative during the admission process. ... I think the relatives feel more valued as a carer and the importance of their role in looking after their relative with dementia is recognised. The patients are also much more relaxed to have familiar faces around so the admission process has become much smoother for everyone including the staff p727<br><br>I have tried to take back to the ward with me topics that I have learned and shared with other members of staff. This has been an eye opener as some staff are not keen to accept change and question everything that I have tried to do and don't seem to see the need for change. P728 | Resources that support knowledge of the patient reduce adverse events such as inappropriate medication, falls, and increased length of stay. Resources that support knowledge of the patient encourage staff to understand behaviour as a form of communication.<br><br>Changing processes and procedures that understand the needs of people living with dementia to reduce patient distress and improve carer satisfaction.<br><br>Difficulty in getting staff to change practices if they do not recognise the need to change practices. |
| Brooker (2014) [63] | "[Dementia awareness training] It has made a big difference to how staff respond to the behaviour of patients with dementia, as it has increased understanding and awareness. For example, there is now a greater focus on occupying patients with activities to reduce behaviour that challenges, and staff are now seen to be walking around with patients with dementia who are wandering when previously they would have told them to sit back down." P48 | Dementia awareness training improves staff understanding of how to better support people living with dementia. Understand the need for providing activities to reduce onset of behaviours that challenge and adapting way of working. |
| Dowding (2016) [60] | Participants discussed how pain may be intermittent and fluctuate, often only being present when patients are engaged in certain activities. ''often the doctors will go round and they'll ask the patient in their bed or in their chair, ''Oh, are you alright? Any pain anywhere?'', ''No, I'm fine''. As soon as we [physiotherapists] come, get them up on it, ''Oh, oh, that really hurts''.[H1, physiotherapist] p156 | Need to understand people living with dementia have difficulty communicating their needs (e.g. pain relief) and will have problems recalling and describing experiences of pain. |

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| | As with other patients, one of the challenges faced by clinicians is the initial recognition of whether or not a patient may be in pain at all; for a variety of reasons patients (including those with cognitive impairment) may not be able to verbally express they have pain, and clinicians often find it challenging to interpret behavioural signals which may be 'atypical' in nature. p157<br><br>One of the key factors in assessing and managing pain is the ability to build a 'picture' or narrative of the patient case; which is used as the basis for the interpretation of cues, to try and 'make sense' of a situation. Participants highlighted the importance of building patterns of information cues and patient behaviour, to help inform their decision making. This narrative occurred over time (an issue which arose in other themes from the data), trying to link different events over the trajectory of a patient stay, to help test 'guesses' and form the basis of trial and error approaches to management. P157<br><br>From the observations it appeared that pain recognition, assessment and management was carried out over time, by many individuals. Rather than being under the control of one specific nurse or other health care professional, it could be characterized more as a process of distributed work, which is time dependent. This is reflected in the comments in interviews, which highlight how there is a division of labour in the hospital ward; there numerous people with different professional roles who are all involved in the care of each patient, each with specific duties, responsibilities and powers. In turn, these roles often governed which part of the pain recognition, assessment and management process they participated in, and how they communicated their findings. p158 | Challenges for staff to understand patient needs.<br><br>Getting to know the needs of the patient through time and continuity in their care.<br><br>Context of ward where responsibilities for the patient's needs are across a number of staff; those who recognise the need may not be able to directly address the need. Importance of communication with colleagues. |
| Duffin (2013) [64] | 'Some people have been moved to tears by the DVDs,'(outcome) says Ms Karasu. 'The films resonate with them. Sometimes you see a look on their face and you can tell they are thinking: "I never thought of that." (reasoning) P16 | Emotional engagement with training and realisation of the patient's experiences of care. |

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| | In one training session nurses, doctors and other staff wear specially designed goggles that restrict their vision, and put on a jacket which has small splints inserted in the arms to restrict movement of their upper body. This is to help staff understand the physical constraints faced by some older people. Darlene Romero, a matron across the trust's three older people's wards, who delivers the training, says: 'It's a real eye opener, and makes you realise how difficult it can be to go to the toilet. P16<br><br>A laminated symbol of a forget-me-not is placed above the beds of all patients with dementia, and a similar motif is put on their casenotes, so that any health worker who comes into contact with them is aware of their condition. Ms Wood says: 'It shows our team that they need to adapt because the person with them has a cognitive impairment. If someone goes to have an X-ray, for example, the team would see the forget-me-not symbol and they would know that this person may not just jump up onto the couch and be ready. They will need to provide more explanation and perhaps to stay a bit calmer than they would with other patients to show extra sensitivity. P17 | Experiential learning triggering realisation of patient needs.<br><br>Identifying a patient has dementia, staff recognising they need to adapt care to be appropriate to the needs of the patient. |
| Edvardsson (2012) [65] | The subtle initial expression of emerging needs were not picked up by staff as they were absent and the expression of unmet needs could escalate to become behavioural alterations as the need remained unsatisfied. When staff finally came about, they were observed to interpret the behaviour as 'disruptive' or 'disturbing' as they lacked the initial interpretative cues that could explain the behaviour. As a consequence, care became very much reactive, as staff had to come up with acute solutions to full-blown situations for which they lacked the insight and an interpretative framework. P6 | Care becomes reactive when behaviour is misinterpreted. Underlying causes not investigated. |
| Ellison (2014) [42] | Colleagues reported improved skills, knowledge and understanding as well as improved confidence in caring for people with dementia as a result of the training and working alongside a Champion. Colleagues also reported changes in their practice as a result of training, for example:<br>spending more time with people with dementia on a one to one basis to provide more | Training supported by a Champion to improve knowledge and understanding of dementia and confidence to work well with people living with dementia. Staff reported changes to care practices. |

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| | individualised care; more effective communication as a result of a better understanding of the needs of people with dementia; involving carers more proactively; understanding the importance of personal care plans and documentation; being more aware of the impact of the environment on people with dementia; being more proactive in providing additional assistance to people with dementia; being prepared to challenge bed moves involving people with dementia when there was no clinical need; increased awareness of signs of stress and distress and seeking to identify the cause rather than resort to use of sedatives. p51 | Staff seeking to address underlying need of people living with dementia rather than treating behaviour with medication. |
| | The primary actions undertaken in this respect have been the implementation of person-centred care planning through use of the 'This is Me' document initially, and subsequent development and implementation of 'Getting to Know Me'. Many DCs have played a key role in implementing and trying to embed these documents through introducing it to their team and training staff in its application. … Use of GTKM allows staff to find out more about the patient and their preferences and is generally considered a useful tool in supporting improved person-centred care for people with dementia. Comments from Champions and their colleagues working in acute settings suggest that use of person-centred plans like this represents a departure from the norm for them in terms of the information they are used to collecting and the conversations they are used to having with patients. Examples were cited where staff have used GTKM more effectively minimise stress and distress, reporting how the information they gained about the patient through the assessment had supported them to recognise and respond more effectively to distressed behaviour. p53 | Use of biographical tools to support person centred care practices that reduce distress.<br>Role of champions in supporting implementation of tool. |
| | In interviews DCs frequently cited the role they have played in influencing the behaviour of colleagues, for example by challenging inappropriate use of language when speaking to or speaking about people with dementia. p54 | Champions role in addressing negative staff attitudes towards people living with dementia. |

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| | "Staff's attitudes have changed hugely in A&E [as a result of DC's awareness raising of how noise and activity can cause distress] – you used to see someone with dementia and there would be 2 or 3 nurses with the one patient, each doing something else and the poor patient... now you see them going in one person at a time, calmer more quietly."p56 | Champion supports staff to understand difficulties faced by people living with dementia. Staff adapt practices to recognise and support difficulties. |
| Galvin (2010) [10] | [post training] The staff also recognized the need for improved communication skills with the patient, such as sitting and talking clearly, using nonverbal clues, and asking permission to touch the patient in order to improve care. | Training for staff to recognise the need to change practices.<br><br>Additional evidence of how training encouraged staff to implement new resources to improve care of people living with dementia (activity packs, volunteers, identification method for patients at risk of leaving the ward). |
| Goldberg (2014) [50] | Staff also appeared more accepting and understanding of mental health problems and patients on the Unit were more likely to raise concerns about their mental health and these would be responded to by staff. This could be because staff were more aware of mental health needs, because they had more conversations with staff in general (and thus the opportunity to raise such concerns) or it could be because they were cared for on a ward where all patients were cognitively impaired. (p1337)<br><br>The Unit provided a greater focus on the mental health needs of patients. Staff were more often observed assessing patients' cognitive abilities (using standardised tools and by questioning) than on standard care. P1337<br><br>Sometimes, skilled care on the Unit was not evident to observers, as patients who had the potential to exhibited distress behaviour were calm. In this observation Alex has been calmly walking up and down the ward for over an hour. A member of staff has always been walking with him and talking to him. Alex's aggression was only evident when something unexpected happened. P1337 | Awareness and understanding of dementia led staff to address patient psychological and mental health needs.<br><br>Use of assessment tools to understand patients' cognitive abilities.<br><br>Supporting patient choice and independence to reduce distress and the onset of behaviours that challenge. |

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| | Individual attention was given to patients at other times on the Unit with staff getting patients drinks or snacks outside of the meal and drink rounds and using touch when interacting with patients. P1338<br><br>However, the psychological needs of the patients on the Unit were high and a minority of patients would call out persistently for long periods of time. Staff would try to comfort or distract them… But the calling out would resume once the staff member left the patient and the conflicting demands on time meant staff would sometimes ignore their cries and attend to other patients, staff or documentation… Delivering care to patients with these behaviours could be exhausting and sometimes, particularly towards the end of a 'long day' (12 1/2 h shift), staff would ignore patients. P1338 | Staff working outside of ward routine to meet individual needs.<br><br>Constraints to addressing patient needs when unable to find out the cause, conflicting demands on staff time, and staff fatigue. |
| Gonski (2012) [66] | Staff members stated that they were sufficiently trained and a majority (n = 11) were able to confidently manage the behavioral problems. The respondents reported that they were able to build therapeutic relationships with both the patients and the carers and were also happy to provide help for both parties. In terms of communication, the nurses were very confident they could communicate with the patients, and therefore were able to interpret individual's needs. P62 | Training supports staff confidence to work with people living with dementia who have behaviours that challenge. Staff ability to communicate well with patients helps them build relationships with patients and understand their needs. |
| Luxford (2015) [67] | Early in the implementation period, a few clinicians reported difficulty in translating the carers' tips into a workable strategy for the hospital environment as they lacked confidence to write strategies based on 'non-clinical' tips. This issue was addressed through further training and the development of lanyards for clinicians to use which demonstrated how to write an effective TOP 5. P5<br><br>After implementing TOP 5, the majority of clinicians reported agreeing or strongly agreeing that TOP 5 was easy to use (91%), not time consuming (70%), decreased patient agitation and distress (74%), resulted in decrease use of restraint—physical or chemical (61%)—and made it easier to relate to carers (89%). P5 | Use of biographical tool supported by champions, training, and examples of how to implement information into care plan.<br><br>Use of biographical tool perceived to reduce patient agitation and distress and the use of restraints. |

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| Nichols (2002) [53] | "We built an interdisciplinary team that looks at the patient and the caregiver as a unit, works with them, and responds to the patient's behaviour as meaningful behaviour that needs to be understood. We understand that dementia patients have special needs. Using a team approach has allowed us to meet those needs in an acute care hospital." p186 | Working with carer to understand patient's needs. Understanding that behaviour is a communication of an unmet need. |
| Scerri (2015) [55] | Care worker (S32): I was thinking about this particular patient who did not need physiotherapy because he was here for respite care. He used to turn to all the staff to ask questions .. So every time I used to engage in a conversation with him and try to first calm him and reassure him because he was panicking and living in a situation as if it is real for him. P6 | Recognising patient needs and addressing them to reassure. Understanding from patient perspective. |
| Schneider (2010) [61] | We found that HCAs continuously ensured that patients were as comfortable as possible, some going out of their way to achieve this. One worker was even known to have sewed and adapted patients' clothing to maximise their comfort (and staff convenience, because this prevented frequent changes of clothing). Efforts were made to overcome language barriers between staff and non-English speaking patients and, when patients were distressed, HCAs often comforted them with actions as well as words: The male patient who becomes very distressed and cries was comforted greatly by H/CO who warmly cuddled up next to him, whilst on his observation, putting her arm around him and letting him snuggle into her, putting his head on her chest. (Fieldnote, Ward C) p28<br><br>We concentrate more, as you get to know the patients, the more you know their ways, you know their habits and if they've got a bad tummy and things like that and you get to know them; the job comes easier when you get to know them. It doesn't stop you getting hit sometimes, but you're aware of, you just get to know them and understand them a bit more. P47<br><br>"Invoking their practical autonomy, the HCAs also made minor adaptations within routines to suit individual patients. For example, medications were administered to all | Recognising and addressing patient needs to improve comfort for patients and benefit staff workload.<br><br>Importance of getting to know patients and benefits to workload.<br><br>Personalising tasks for needs of patients. |

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| | patients at approximately the same times every day on each ward, rather than being doled out individually; this ensured that every patient received his or her medication, as well as conserving staff time. However, within this routine, HCAs who were 'running' the medications would often make small concessions, for example by taking extra time to gain the trust of individual patients." P 49 | |
| Spencer (2013) [52] | Carers of patients with MMHU described staff as being 'well prepared' for dealing with confused patients, displaying patience and compassion. Respondents noted that patients who liked to wander were guided by staff when walking up and down rather than constantly being returned to their bed space, a behaviour observed by carers on standard care wards. P3<br><br>"Participants felt that staff had little understanding and limited training in dementia care, which carers felt resulted in patients being ignored, shouted at or threatened when staff were faced with uncooperative or challenging situations." P3 | Staff who have understanding of dementia and dementia care can meet the needs of patients.<br><br>Where staff lack understanding of behaviours that challenge they misinterpret them and attribute the problem to the patient, leading to poor care. |
| Waller (2015) [49] | Many of the environmental changes appear to have occurred as a consequence of the training that teams received before they started planning their projects. For example changes in staff attitudes such as investing in table cloths, laying tables, and purchasing coloured crockery, as well as increases in activities for patients such as the provision of newspapers or implementation of therapy hours, were reported; in the words of one team member, it is 'not just about the colour of the paint'. P64<br><br>Making spaces seem smaller and more familiar, and reducing the numbers of decisions that have to be made by patients in finding their way to places such as the toilet, the dining room or their own bed space, seems to significantly reduce agitation. P65 | Staff training helps staff recognise the needs of people living with dementia and make adaptions.<br><br>Changes that recognise the difficulties of people living with dementia will help reduce distress. |
| White (2016) [12] | Patients with any form of BPSD during their admission were five times more likely to have an antipsychotic prescribed during the admission (OR 4.99, 95% CI 1.15, 21.70, p=0.032). Antipsychotic prescription was five times more likely in people who | Behaviours that challenge increase likelihood of antipsychotic prescription. |

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| | experienced hallucinations (OR 5.04, 95% CI 2.10, 12.06, p≤0.001) or activity disturbances (OR 5.71, 95% CI 2.22, 14.70, p≤0.001) and seven times more likely with aggressive behaviours (OR 7.70, 95% CI 2.25, 26.31, p=0.001). Patients were three times more likely to have an antipsychotic prescribed when they experienced sleep disturbance (OR 3.35, 95% CI 1.45, 7.79, p=0.005).<br><br>In total, 55% of participants received non-pharmacological management during their admission. The most commonly used techniques were psychosocial interventions (36%) and staffing (17%) (Table 2). We found no evidence in the nursing or medical notes of ongoing monitoring or review of the effectiveness of these non-pharmacological interventions, or of a systematic way of using these techniques. | Lack of monitor of non-pharmacological management of behaviours that challenge so difficult to know effectiveness. |
| Williams (2011) [39] | We are testing a REACH education programme for domestic assistants and housekeepers… They had not considered the positive impact they could have in contributing to care and, without exception, were delighted to support the initiative. P15<br><br>REACH helps all staff to understand the cognitive difficulties experienced by people with dementia. It enables them to contribute in their role and promotes pride in the part they play in care. p15<br><br>Carers feel relieved that their loved one's condition is recognised and that hospital staff know how to respond to them, while the carers' sheet allows families to pass on crucial information and tips that will keep patients safe and improve their care'. P17 | Understanding the problem, knowing how can make a difference to patient experience and being able to take pride in work.<br><br>Working with carers to get to know the patient and know strategies that work well to improve patient safety. |

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Supplementary file 5: Characteristics of included papers

| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Baillie, 2015 [59] | UK | Published report | Evaluation of Barbara's Story | Qualitative | Written responses and focus groups | Patient satisfaction, patient safety |
| Baldwin, 2004 [48] | UK | Published paper | RCT of mental health liaison team | Quantitative | Validated tools | Depression, cognitive impairment, referrals |
| Banks, 2014 [40] | UK | Published paper | Evaluation of dementia champion training programme | Evaluation | Questionnaires of trainee knowledge and confidence in dementia, qualitative analysis of trainee reports | Impact of intervention on PLWD |
| Bray, 2015 [62] | UK | Published paper | The use of bay nursing and activity with PLWD in hospital | Description of the use of bay nursing and activities co-ordinators | Dementia care mapping, Patient experience questionnaires | Patient satisfaction |
| Brooker, 2014 [63] | UK | Published report | Evaluation of Royal College of Nursing development training programme | Evaluation report | Online survey, site evaluation (including locally determined methods such as dementia care mapping, | Patient satisfaction, carer engagement, reduced distress |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | incident reporting and patient satisfaction survey) | |
| Dowding, 2016 [60] | UK | Published paper | Development of pain management tool for PLWD in hospitals | Ethnographic study | Interviews, non-participant observation, medical notes review, documentary analysis | The identification and management of pain |
| Duffin, 2013 [64] | UK | Published paper | Description of interventions to improve care for PLWD in hospitals | Discussion paper | n/a | Patient satisfaction, patient safety |
| Edvardsson, 2012 [65] | Sweden | Published paper | Understanding the psychosocial climate of a ward | Qualitative | Observation | Patient satisfaction |
| Elliot, 2011 [45] | UK | Published paper | Description of role of Dementia Nurse Specialist | Discussion paper | n/a | Patient experience, patient safety, needs assessments, patient involvement in decision-making |
| Ellison, 2014 [42] | UK | Published report | Evaluation of Dementia Champions and | Evaluation | Interviews, staff survey | Patient experience, assessment of |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | Dementia Nurse Consultants | | | needs, reduced distress, reduced behaviours that challenge |
| Enns, 2014 [71] | Canada | Published paper | Quality improvement trial to reduce the use of physical restraints in hospital | Step wedged trial | Medical notes review | Use of restraints |
| Galvin, 2010 [10] | USA | Published paper | Evaluation of dementia awareness training programme | Pre-, post-, and delayed post test | Questionnaires of staff knowledge and confidence in dementia, interviews with trainees | Patient experience, |
| Goldberg, 2014 [50] | UK | Published paper | Patient experience and care on a Medical and Mental Health Unit compared with care on general wards | Qualitative findings from RCT | Non-participant observation (structured (dementia care mapping) and unstructured) | Patient experience, reduced distress, reduced behaviours that challenge, supporting patient choice (walking about the ward, food outside of mealtimes) |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Goldberg, 2013 [51] | UK | Published paper | Patient outcomes on a Medical and Mental Health Unit compared with general wards | Quantitative findings from RCT | Interviews, medical notes review, used of validated tools, non-participant observation (dementia care mapping) | Days spent at home, health status outcomes, behavioural and psychological symptoms, physical disability, cognitive impairment, carer strain, carer psychological wellbeing, carer satisfaction, patient mood and engagement |
| Gonski, 2012 [66] | Australia | Published paper | Outcomes of PLWD treated on a behavioural unit in a hospital | Retrospective review of medical records | Medical notes review, interviews with staff and carers | Carer satisfaction, Patient health care outcomes, behaviours that challenge, mediation, falls |
| Harwood, 2010 [72] | UK | Unpublished report | Development of Medical and Mental Health Unit | Discussion paper | n/a | Patient experience, patient orientation to |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | | time, supporting patient abilities, patient safety, supporting patient choice (walking about the ward), patient referrals, behaviours that challenge, medication review, carer satisfaction, carer involvement |
| Luxford, 2015 [67] | Australia | Published Paper | Clinician-carer communication tool | Survey | Survey with staff and carers | Acceptability and perceived benefits for patients |
| Moyles, 2011 [68] | Australia | Published paper | Best practice, the use of 'specials' | Qualitative Interviews | Interviews with staff | Patient experience |
| Nichols, 2002 [53] | USA | Published paper | The development of a specialist dementia care unit | Discussion paper | n/a | Improved communication with carers, improved patient experience |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Rosler, 2012 [69] | Germany | Published paper | Treatment of PLWD with hip fractures on specialist ward compared with general ward | Matched pair analysis | Validated scales | Functional status, use of antipsychotic medication, length of stay |
| Scerri, 2015 [55] | Malta | Published paper | Person centred care in hospital wards | Appreciative Inquiry / Qualitative interviews | Interviews | Family carer satisfaction, patient experience |
| Schneider, 2010 [61] | UK | Published report | The role of health care assistants in caring for people living with dementia | Ethnographic study | Participant observations, Interviews | Patient experience |
| Spencer, 2013 [52] | UK | Published paper | Family carer perceptions of care on Medical and Mental Health Unit compared with general wards | Qualitative findings | Interviews with family carers | Carer satisfaction, carer perception of care |
| Upton, 2012 [70] | UK | Published report | Multi-component bundle of evidence-based interventions | Qualitative and quantitative findings | Interviews, survey, medical records | Ward moves, infections, weight, catheter use, falls, mobility, place of discharge, use of antipsychotics, patient and carer satisfaction |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Waller, 2015 [15] | UK | Published paper | Dementia friendly environmental adaptions in healthcare settings | Summary of findings of evaluations | Pre and post audit and locally determined data collection (observations, incident forms and falls data, medication review, interviews) | Behaviour that challenges, falls, patient engagement in activity, reduced agitation and distress, reduced use of antipsychotics |
| White, 2016 [12] | UK | Published paper | Management of behavioural and psychological symptoms of dementia in hospitals | Longitudinal cohort study | BEHAVE-AD scale<br>Non-participant Observation<br>Medical notes review | Behaviours that challenge and the use of pharmacological and non-pharmacological interventions for behavioural management |
| Williams, 2011 [39] | UK | Published paper | Development of the Butterfly Scheme | Discussion paper | Staff self-report for use of the scheme | Patient experience, identification and interpretation of behaviours that indicate a need (managing pain and continence), |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | | reducing patient distress, patient safety, carer satisfaction |
| Zieschang, 2010 [54] | Germany | Published paper | Feasibility study of dementia care specialist unit | Feasibility study | Staff survey, validated tools | Patient function, patient mobility, behaviours that challenge, length of stay, falls, use of restraints, use of antipsychotics |

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BMJ Open

# Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review



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Title Page

**Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review**

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**Abstract**

Objectives: To identify features of programmes and approaches to make healthcare delivery in secondary healthcare settings more dementia friendly, providing a context-relevant understanding of how interventions achieve outcomes for people living with dementia.

Design: A realist review conducted in three phases (1) stakeholder interviews and scoping of the literature to develop an initial programme theory for providing effective dementia care; (2) structured retrieval and extraction of evidence; (3) analysis and synthesis to build and refine the programme theory.

Data sources: PubMed, CINAHL, Cochrane Library, NHS Evidence, Scopus, grey literature.

Eligibility criteria: Studies reporting interventions and approaches to make hospital environments more dementia friendly. Studies not reporting patient outcomes or contributing to the programme theory were excluded.

Results: Phase 1 combined findings from 15 stakeholder interviews and 22 publications to develop candidate programme theories. Phases 2 and 3 identified and synthesised evidence from 28 publications. Prominent context-mechanism-outcome configurations were identified to explain what supported dementia-friendly healthcare in acute settings. Staff capacity to understand the behaviours of people living with dementia as communication of an unmet need, combined with a recognition and valuing of their role in their care prompted changes to care practices. Endorsement from senior management gave staff confidence and permission to adapt working practices to provide good dementia care. Key contextual factors were the availability of staff and an alignment of ward priorities to value person-centred care approaches. Preoccupation with risk generated responses that were likely to restrict patient choice and increase their distress.

Conclusions: This review suggests strategies such as dementia awareness training alone will not improve dementia care or outcomes for patients with dementia. Instead, how staff are supported to implement learning and resources by senior team members with dementia expertise is a key component for improving care practices and patient outcomes.

PROSPERO Trial Registration Number: CRD42015017562

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**Strengths and limitations of this study**

- Applying realist methods enabled a theory-driven explanation of how dementia-friendly healthcare can be supported in hospital settings
- The process of the review facilitated the development of a new programme theory, which can be used to inform future initiatives that support people with dementia in hospital environments
- The involvement of stakeholders from the outset ensured the plausibility and relevance of the findings for hospital environments
- The extent of evidence to support some elements of the programme theory was limited, especially where interventions lacked specificity about process and patient outcomes.

**Key words**

People living with dementia, hospitals, dementia, realist review, dementia friendly

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## INTRODUCTION

There is increasing recognition that hospital staff and services need to understand the complexity of caring for and treating people living with dementia [1]. At any one time, 25% of hospital beds are used by people living with dementia, rising to a higher proportion on some wards [2]. Co-morbidities are common and many people are admitted to hospital for reasons not directly related to their dementia [3-5]. Healthcare outcomes for people living with dementia are variable across the country and are inequitable when compared to outcomes for people without cognitive impairments [5]. Adverse incidents occurring during admissions, such as falls, poor nutrition and hydration, infections, and the onset of delirium, contribute to longer stays and reduced functional abilities which may result in admission to a care home [6-8].

A number of factors may impact on the disparity of health outcomes for people living with dementia including: a lack of focus and leadership for dementia in hospitals [5]; healthcare staff who have inadequate knowledge and training in dementia and dementia care [9, 10]; difficulties faced by healthcare professionals when assessing the risk and benefits of treatment options [11]; widespread use of care practices which are detrimental to people living with dementia, such as the use of antipsychotics for behavioural management [12]; stigma and discrimination towards people living with dementia [13, 14]; and confusing, unsafe environments [15]. The National Dementia Strategy [16] aimed to improve the quality of care for people living with dementia in general hospitals through leadership that addresses quality improvements in dementia care, defined care pathways, and the use of liaison mental health teams. It also highlighted the importance of education and training to break down the stigma associated with dementia and to develop dementia awareness within the healthcare workforce. To address these ambitions, interventions have been designed and implemented with the aim of creating dementia-friendly healthcare in hospitals [17, 18].

### Dementia Friendly

The concept of dementia friendly developed from initiatives to promote age-friendly communities [19]. It was first used to describe physical and social environments that promoted inclusion, acceptance and accessibility for people living with dementia [20, 21] and includes initiatives supporting the independence and safety of people living with dementia [22]. In the UK, this includes the Dementia Friends initiative [23] and the Dementia Engagement and Empowerment Project (DEEP) [24].

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At the patient level, dementia-friendly healthcare is the practice and organisation of care that is aware of the impact dementia has on a person's ability to engage with services and manage their health. It promotes the inclusion of people living with dementia and their carer in treatments, care decisions and discussions, with the aim of improving outcomes for the patient and carer [16, 17, 25-27].

Interventions to promote dementia-friendly healthcare environments have been diverse in terms of their design and application in practice [27-29]. This review of the evidence acknowledges that the effectiveness of programmes to address the known problems of being a patient with dementia is contingent on multiple factors such as staff knowledge and skills in dementia care, the care environment, and the competing demands on staff time and attention. The review objectives were:

1. To identify how dementia-friendly interventions in hospital settings are thought to achieve the desired patient and carer outcomes
2. To develop evidence-based explanations to understand what it is about dementia-friendly interventions in hospitals that works for people living with dementia and their carers, in what circumstances and why.

**Realist Methodology**

Realist review is a theory-led method that applies the principles of realism to evidence review [30, 31]. In realism, change is not directly achieved by an intervention, rather change is generated through the influence of intervention resources and contextual factors on human reasoning. A realist approach seeks to explain how the relationship between these elements (context and mechanism) leads to particular outcomes (box 1) [30].

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Box 1: Glossary of realist terms

Context: refers to factors, including but, not limited to, personal, social, organisational, or policy aspects that influence the way resources are engaged with to generate outcomes. For example, staffs' professional focus may influence how they use information about a person's social, rather than medical, history, or an organisation's expectations for dementia care may affect how staff prioritise their work with patients with dementia.

Mechanism: includes the resource the intervention provides (such as training, assessments of pain, or access to biographical information about the patient) and the reasoning of the subjects, in this case the reasoning of staff (such as recognising the benefit of working differently) [32].

Outcome: the intended (or unintended) result. Patient outcomes of interest included; patient wellbeing, medication use (specifically analgesic and anti-psychotic), access to assessments, evidence of inclusion in care decisions, reduced distress, adverse incidents (such as falls or hospital acquired infection), length of stay, reduction in the onset of behaviours that challenge, maintenance of functions (such as activities of daily living).

Demi-regularity: a semi-predictable pattern of outcomes. For example, the provision of meaningful activities for patients with dementia will reduce their boredom and distress in hospital, leading to a reduction in the onset of behaviours that are challenging for staff.

Context-mechanism-outcome configuration: specifies the relationship between the features (context, mechanism and outcome). It is the unit of analysis which supports synthesis across studies to build and refine the programme theory.

Realist review was appropriate for this study as the evidence base for dementia-friendly interventions is in its early stages. As such, theory building derives from a variety of sources and study types. Complexity is inherent in both design and implementation of the interventions: they are multicomponent and rely on human agency that is influenced by individual, service and organisational pressures. Realist inquiry acknowledges these features and incorporates them to develop an explanatory account of how different aspects influence reasoning and outcomes [33].

## METHOD

Realist review methods were used to develop a theoretical understanding of what supports effective dementia care in hospital settings. There were three overlapping, iterative phases: 1) defining the scope of the review informed from key literature and stakeholder interviews; 2) structured searches, screening, and data extraction; 3) analysis and synthesis leading to refinement of the programme theory. A fuller account of the review protocol is available in Handley, et al. [34].

The phases did not follow a linear format, but informed and refined understanding throughout the review leading to new interpretations and building of evidence. Sources were identified and revisited, new evidence was incorporated, and inclusion criteria reconsidered as new theoretical understanding developed. The RAMESES publication standards informed the preparation of this report and has been vetted against RAMESES criteria (supplementary file 1 and supplementary file 2) [31].

### Changes to the review process

One change was made to the review process subsequent to the published review protocol [34]. The expert steering group workshop was not held. However, emerging findings and the refined programme theory were shared with the with Alzheimer's Society research network monitors (RP, JW, PM) who were volunteer representatives with experience of caring for family members living with dementia. They commented on the resonance and relevance of the inferences that contributed to the developing theory throughout the review process. Review findings were presented and discussed at a seminar on dementia-friendly healthcare with 75 participants, 19 of whom worked in hospitals. The findings are being taken forward for testing in a realist evaluation.

### Phases of the Realist Review

*Phase one: Defining the scope of the review: concept mining and theory development*

Evidence from interviews with stakeholders and a scoping of the literature was used to: 1) identify the range of dementia-friendly interventions in healthcare settings both in the UK and internationally, 2) determine possible theoretical assumptions about how and why interventions were thought to work (or not), and 3) clarify what were understood to be the significant mechanisms for change. Stakeholders, defined as people with experience in designing, implementing, and using dementia-friendly interventions, were identified from knowledge within the team, internet searches, and dementia-specific conference abstracts. They were purposively sampled from a range of settings (academia, healthcare, commissioning, social work, the community) and backgrounds (nursing, education,

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physiotherapy, research, person living with dementia) [34]. Stakeholders were not further involved in the development of the emerging context-mechanism-outcome configurations (CMOCs) or building the programme theory. Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

Data from interviews and the literature were coded using framework analysis [35] with emerging themes and competing accounts discussed and debated amongst the authors (MH, FB, CG) and with Alzheimer's Society research network monitors (RP, JW, PM). Mapping this evidence demonstrated limited understanding at the point of staff interaction with patients and how this influenced patient outcomes. A decision was made to focus the review on how interventions led to patient outcomes. Data from the interviews and literature were scrutinised for demi-regularities (see Box 1, glossary of realist terms) and informed hypotheses set out in the form of 'If… then statements'. These statements were used to define the conditions thought to be necessary to achieve: 1) staff outcomes, such as taking action to investigate the cause of patient behaviours and applying best practice with people living with dementia; and 2) patient outcomes, such as reduced distress, reduction in adverse incidents, and improved wellbeing. Discussions amongst the authors based on these statements led to the development of a conceptual framework [30]. Three overlapping theoretical propositions were generated to explain what supports the implementation and uptake of interventions that promote dementia-friendly healthcare within a ward based environment.

*Phase two: Retrieval and review*

*Searching for relevant studies*

Informed by the theoretical propositions derived from the work in phase one, search terms were revised. The inclusion/exclusion criteria were refined to focus on studies which reported patient outcomes and provided information about the characteristics and role of change agents (staff who supported the implementation and uptake of interventions).

Searches were limited to 2000 – 2015 to reflect the impact of the work of Kitwood and Bredin [36] on dementia care practices that recognise the importance of person-centred care and the promotion of personhood. In addition to the electronic database searches (box 2), we undertook extensive lateral searching, including forward and backward citations, and contact with experts. Additional searches were performed as emerging themes around the management of pain and behaviours that challenge became apparent. These were

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purposive searches that applied the same inclusion criteria. Theory development continued until theoretical saturation was achieved [37, 38] (box 2).

Box 2: Phase two search terms and search strategy

Searches initially run September 2015, search alerts scanned to February 2016

Language restricted to English

Date restricted 2000 – 2015

Search terms:

(dementia AND (friendly OR appropriate OR awareness OR champion OR liaison OR ward OR environment OR education OR training OR nurse specialist OR lead* OR person centred care) AND (hospital OR acute care OR secondary care))

Additional search terms developed from work in phase one:

dementia AND (change agent OR champion OR knowledge transfer OR knowledge translation OR opinion leader)

Additional search terms reflecting emerging themes in phase two. Searches ran January 2016, search alerts scanned to February 2016

(dementia AND (pain) AND (hospital OR acute care OR secondary care))

(dementia AND (behaviour* OR BPSD) AND (hospital OR acute care OR secondary care))

Databases:

Cochrane Library (incl. CENTRAL, CDSR, DARE, HTA) (244), CINAHL (610), PubMed (4253), NHS Evidence (819) and Scopus (410)

*Study screening and data extraction*

Search results were downloaded into EndNote bibliographic software and duplicates deleted. One author (MH) screened titles and abstracts identified by the electronic search and applied the selection criteria to potentially relevant papers. Full texts of potentially relevant manuscripts were screened for relevance (whether the study has contributed to specific propositions relevant to the theory building) and rigour (whether they were of sufficient quality to provide credible evidence to help refine specific components of the

proposition) [30, 31]. Appraisal of the contributions and reliability of evidence from papers continued throughout the synthesis through discussion with the other authors.

Data were extracted by one author (MH) using a bespoke data extraction form organised to establish contributions and challenges to the theories, and strengths and weaknesses of the studies. Study characteristics such as design, setting, participants and sample size were also recorded [31]. The data extraction form was piloted by MH and shared with the team for comment [supplementary file 3]. To reduce the potential for bias during data extraction, a sample of the papers and their completed data extraction forms (6/28) were shared with FB and CG to appraise the extraction process and identified data. Information about the role and work of the change agent, the resources provided by the interventions, the contextual features of the settings (e.g. workforce, knowledge of dementia), explicit and implicit theories for how interventions were anticipated to work, and patient and carer outcomes were extracted. Coded data from all the papers and their contribution to theory development were shared with FB and CG. Challenges to interpretations were discussed to test credibility. Evidence from the studies were first mapped to capture the complete range of possibilities of how different approaches and resources triggered different responses from patients, family, and staff. After discussion amongst the authors, data were organised into tables to reflect the theoretical propositions they addressed (supplementary file 4) and to assist comparison of data across studies.

*Phase 3: Analysis and Synthesis*

Data synthesis was led by MH and emerging findings were discussed with the team (CG and FB), and the research network monitors (RP, JW, PM). Deliberations assisted the refinement of propositions, ensuring that emerging theories were plausible and clear. Discussions of papers included: the key characteristics of members of staff who support the implementation and uptake of interventions, resources, and new ways of working with people living with dementia (change agents); resources from interventions and how they were thought to influence staff reasoning; the impact of context; and possible undesired outcomes (such as stigmatising practises and broad application of strategies at the expense of individual needs). The focus was on understanding how patient outcomes were achieved through the actions of staff and what had supported staff to behave in particular ways. Recurring patterns in context and outcome (demi-regularities) detectible across studies were explained by explicit or implicit mechanisms. This led to the development of context-mechanism-outcome configurations designed to explain what it is about an intervention that

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works, for whom, and in what circumstances. The configurations were used to refine components of the initial theoretical propositions against the evidence.

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## FINDINGS

### Phase 1

Evidence from 15 stakeholders was combined with literature on interventions aimed at improving healthcare for people living with dementia (22 papers) to generate three initial propositions for developing dementia-friendly hospital environments. Interventions described in the literature can be seen in table 1.

Table 1: Papers included in Phase 1

| Intervention | Papers |
|---|---|
| Schemes to identify people with dementia admitted to the ward: e.g. a butterfly symbol above patient's bed to help identify people who have dementia, linked to a training programme and the collection of biographical history from the family carer. | [39] |
| Dementia Champion: healthcare staff (mainly nursing staff) are trained to champion dementia care issues, providing support to peers. | [27, 40-44] |
| Dementia Specialist Nurse: senior nurse working across the hospital as an expert in dementia to advise staff on treatment, care practices, and liaise with community services. | [45, 46] |
| Staff training and education: training in dementia awareness and dementia care. | [9, 10, 28] |
| Liaison psychiatry / mental health teams: specialist teams working across the hospital to assess mental health of patients and advise staff on treatment and care. | [47, 48] |
| Environmental adaptions: changes to clinical areas including signage, new furniture, and improved flooring and lighting. | [15, 49] |
| Specialist units for people living with dementia: include physical adaptions and specialist staff to treat the medical and psychological needs of people living with dementia | [50-54] |
| Use of person centred care: model of care that prioritises the needs of the person. | [55] |

A key contextual factor to emerge from Phase 1 related to the role of change agents, although there were competing accounts of how a change agent might work and the

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responses they might trigger in staff. There appeared to be three distinct roles for change agents' activities that could lead to improved outcomes, these were:

- To support staff awareness and learning,
- To possess the authority to institute and sustain changes,
- To be a resource for staff as a clinical expert.

Change agent characteristics (e.g. supportive peer facilitator, organisational authority, clinical expertise) were considered to differently influence how staff engaged with interventions and this, in turn, would impact on patient outcomes (table 2).

Table 2: Initial theoretical propositions developed from phase 1

| Dementia-friendly interventions in hospitals improve outcomes for people living with dementia and their carers if… | Evidence from stakeholders and preliminary scoping and supporting references |
|---|---|
| … a change agent supports staff to reframe their understanding of dementia and respond appropriately to people living with dementia through learning and resources which address patient needs in an individual way. **Then** staff will have increased awareness of dementia and the impact dementia has on a person, and build confidence in their ability to recognise and address distress. | Emphasis on training and education that improve staff confidence in working with people living with dementia. Breaking down negative assumptions and supporting staff to see the person rather than the diagnosis. Use of resources to get to know the person.<br><br>References: [9, 10, 28, 39-42, 44, 55-57]<br><br>Stakeholders (SK01, SK02, SK03, SK04, SK05, SK06, SK07, SK09, SK10, SK11, SK12, SK13, SK14)<br>Example quote: "we're starting to do some training with our staff as well just to try and help everyone to know how to approach and how to feel empathy towards these patients who have dementia." (SK12) |
| … a change agent with organisational and clinical authority communicates the priorities for dementia care and addresses staff concerns | Strategic planning, prioritising good dementia care, providing resources that support staff to work in new ways, changes to systems and |

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| | |
|---|---|
| around managing risk and workplace disruption in person-centred ways. Staff are supported by training and resources that improve the involvement in decision-making and safety of people living with dementia, **then** staff will understand they have the permission and encouragement to adapt practices in ways that are beneficial for people living with dementia. | processes<br><br>References: [15, 42, 49-55]<br><br>Stakeholders (SK05, SK06, SK07, SK08, SK10, SK11, SK14, SK15)<br>Example quote: "…however good people's ideas are, if they don't have some kind of sign-off at a fairly senior level then they're not really going to have it 'cos they'll never be a priority and because there are so many targets to be met in general, unless there's some kind of strategy or policy in writing I don't think it can change much really." (SK08) |
| … a change agent with clinical expertise in dementia and dementia care supports staff with assessments and care planning **then** staff will identify and resolve the care needs of people living with dementia. | Assessments of cognition, mental health, and psychosocial needs. Role modelling good dementia care. Supporting staff to perform care in a person-centred way, direct care planning and address complex issues such as decisions of best interest, access to mental and social care information.<br><br>References: [45, 47, 48, 50-52, 58]<br><br>Stakeholders (SK04, SK09, SK11, SK14, SK15)<br>Example quote: "we had mental health nurses came to work with us and they had a really important part in role-modelling how it looked, how to approach things." (SK14) |

**Phase 2**

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Evidence from 28 papers, 12 of which were identified and included in phase one of the review (supplementary file 5), led to the development of six context-mechanism-outcome configurations (CMOCs) that explored the components of the three theoretical propositions developed in phase one (an overview of the selection process can be seen in Figure 1). These configurations are interconnected, representing key elements from the theories and how they relate to other factors (table 3). The CMOCs and supporting evidence are discussed below. Illustrative examples of evidence from the literature that guided CMOC development are supplied in Supplementary file 6.

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Table 3: Context-mechanism-outcome configurations and supporting evidence

| Brief title | Full Context-mechanism-outcome configuration | References |
|---|---|---|
| Understanding behaviour as communication to improve staffs' ability to respond | Where behaviours that challenge are understood as communication of an unmet need (context), through training, resources and support from experts in dementia care (mechanism resource), staff will feel they have improved capacity and capability to influence the situation (mechanism reasoning) making it more likely they will identify and address the need (outcome).<br>However<br>Conflicting work demands, patient characteristics (context) and staffing resources (mechanism resource), may lead staff to feel they are unable to make a difference (mechanism reasoning) meaning patient need might not be recognised, investigated or addressed (outcome) | [10, 15, 39, 40, 42, 45, 50, 52-55, 59-70] |
| The role of experiential learning and creating empathy to encourage reflection for responsibilities of care | Access to training (context) which promotes experiential learning and empathy towards people living with dementia (mechanism resource) can encourage reflection which identifies deficiencies in current working practices, helping staff to understand their responsibilities for care (mechanism reasoning), leading them to take more time with people living with dementia (outcome).<br>However<br>Where good dementia care practices (mechanism resource) are not considered legitimate working practices (context), staff may consider these | [10, 39, 40, 55, 59, 62-64] |

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| | | |
|---|---|---|
| | practices as additional to their workload (mechanism reasoning) leading to inconsistent provision of care (outcome) | |
| Clinical experts who legitimise priorities for care | Clinical experts who have the authority to legitimise priorities and standards for dementia care endorsed by the organisation (context), provide support for staff to develop skills in dementia care (mechanism resource), can help staff feel confident of the expectations for their role (mechanism reasoning) to adapt working practices (outcome)<br>However<br>By focusing the responsibility for dementia care in select staff (context/mechanism resource), there may be a reduced sense of responsibility for dementia care in the wider workforce (mechanism reasoning) reducing the ability of experts to embed good dementia care practices across the organisation (outcome) | [40, 42, 45, 48, 50, 53-55, 59, 61-64, 69-71] |
| Staff with confidence to adapt working practices and routines to individualise care | Staff supported to be flexible in their role and working environment (context), where their responsibilities for patient care have been clarified (mechanism resource) may be responsive or adaptive in their decision making (mechanism reasoning) to provide care and treatment to a person in a timely, individualised manner (outcome)<br>However<br>Changes to staff capacity or environmental adaptions (context/mechanism resource) may need to be recognised and addressed by management (mechanism reasoning) to support staff to provide responsive care | [50, 55, 61, 62, 69] |

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| | | |
|---|---|---|
| | (outcome) | |
| Staff with responsibility to focus on psychosocial needs | Where there is provision of activities and therapies for people living with dementia that supports their interests and abilities (context) by staff with a role to address psychological, emotional and social issues (mechanism resource) and responsibility (mechanism reasoning) for maintaining functional and cognitive abilities, (outcome), this can provide other healthcare staff with time to prioritise physical and medical needs (outcome).<br>However<br>Where staffing resources are limited (context), staffing for activity and therapy can be reallocated to maintaining patient safety (mechanism resource) which may require staff to prioritising safety concerns (mechanism reasoning), limiting their ability to meet psychosocial needs (outcome). | [10, 50, 51, 54, 55, 62, 64, 65, 68, 70, 72] |
| Building staff confidence to provide person-centred risk management | Where procedures and expectations for care are set out to address risk in a person-centred way (context), and is encouraged and reinforced through ward leadership (mechanism resource) staff may feel confident to address risk proportionately (mechanism reasoning) and may support patients with dementia to maintain function and abilities in a less restrictive way. (outcome).<br>However<br>Resources will need to be compatible with environmental features and staff capacity (context/mechanism resource) or staff may not feel there is a value | [10, 15, 39, 50, 51, 53, 54, 64, 66-68, 70, 71] |

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| | | |
|---|---|---|
| | to their work or for the patient (mechanism reasoning) making it unlikely they will adapt care practices (outcome) | |

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*CMOC 1. Understanding behaviour as communication to improve staffs' ability to respond*

Studies frequently reported that where staff understood behaviour that challenged as communication of an unmet need, they were more likely to investigate the underlying cause rather than attempting to control and restrict the behaviour [15, 40, 42, 53, 60, 66, 70]. By addressing the unmet need, staff reduced patient distress [50, 55, 59, 62, 63, 65, 70] and maintained independence, for example by supporting mobility and toileting needs [39, 54, 64, 69]. Inappropriate and negative staff responses arose from lack of understanding and misinterpretation of behaviours that challenge, for example, interpreting the patient as being deliberately difficult [52, 68].

Strategies employed to reframe staff understanding of behaviours included: training in dementia [10, 15, 55, 59, 62]; the use of biographical tools, completed in partnership with informal carers, [39, 40, 53, 67, 70]; assessments of cognition, pain, and psychological needs [50, 51, 54, 60]; and access to experts in dementia care [40, 42, 45, 50, 54, 70]. Common to these interventions were that they supported staff to consider potential causes of behaviours and provided strategies to address the unmet need, such as the development of individualised care plans [45, 67] and personalised strategies for reducing distress [39, 70]. Training to recognise behaviours as the expression of an unmet need [59, 61], and knowledge of a patient gained through continuity in their care [55, 61, 62] helped staff become aware that particular care practices were unsuitable and to adapt their work in a way that benefitted the individual. However, personalisation of practices appeared to occur in pockets of activity rather than as an ethos of care provision. Even when staff understood and were supported to work well with people living with dementia with behaviours that challenged, their ability and willingness to address psychological needs was limited. Conflicting work demands, staff fatigue, long shifts, and difficulty in identifying and resolving patient issues resulted in staff responding to behaviours by ignoring and disengaging from the patient [50, 65].

*CMOC 2. The role of experiential learning and creating empathy to encourage reflection for responsibilities of care*

Staff training that improved awareness of the impact of dementia and which addressed negative concepts was found to be a prerequisite for supporting good dementia care. While the literature suggested training had a positive impact on knowledge and confidence for

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working with people living with dementia, more work is need to understand how this works in practice [10, 39, 40, 59].

Training strategies which employed experiential learning techniques and cultivated empathy in staff for people living with dementia prompted reflection on current practices. Evidence suggested these training sessions produced 'lightbulb moments' for staff where they gained a sudden realisation of the problems faced by people living with dementia [40, 59, 64]. This appreciation for the importance to adapt care practices prompted staff to work in ways that would better support the patient, and improved staff satisfaction with their work [39, 72]. Additionally, one study reported how staff associated the portrayals of people living with dementia in training materials to their own relatives. This encouraged staff to see people living with dementia as individuals and motivated them to take responsibility to put their learning into practice [59].

The use of reflection and examples of good care practices in recognisable situations gave staff a framework for working well with people living with dementia and demonstrated the benefit to their own work [59, 64]. However, these practices were often referred to by staff as 'going the extra mile' or being additional to their workload rather than being an expectation of their role. Staff needed to be confident additional time spent with patients would not be viewed negatively by colleagues or impact on the requirements to manage the ward effectively, to support adaptions to care practices [55, 59].

*CMOC 3. Clinical experts who legitimise priorities for care*

Change agents influenced staff working practices through clinical expertise and organisational authority [40, 42, 45, 48, 50, 54, 62, 63, 70]. Experts in dementia care supported staff in the use of assessment tools and person-centred care planning [48, 54], role modelled appropriate behaviour and communication for working with people living with dementia [40, 50], and provided professional advice for complex situations, such as decisions around best interests [42, 45]. Access to experts in dementia care was suggested to reassure and encourage staff to provide good care for people living with dementia. Endorsement of these practices were communicated by clinical experts with a level of organisational authority at ward level [54, 55, 59, 62, 71] and across the organisation [53, 59, 63]. They addressed staff apprehensions to adaptions to care practices that previously prioritised medical and physical needs, ward routines, task focused ways of working, and organisational expectations for the completion of documentation and risk reduction [53, 54,

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62, 63, 71]. Our review found when change agents in authority communicated new expectations for standards of care and changes to procedures, they validated the priorities for care and legitimised staffs' adaption of care practices accordingly [53, 54, 59, 71]. However, the impact of changes to staffs' work needed to be recognised and supported [50, 53, 54, 62, 69-71]. For example, studies reported there was reduced capacity to work with previous levels of patient allocation [53, 62, 69], and changes to risk management strategies, such as encouraging mobility in a frail patient population at risk of falls, required staff training [54, 71].

There was limited evidence that new practices were adopted by staff and embedded into everyday practice directly through their contact with dementia experts. Instead, it appeared that the experts maintained responsibility for dementia care, either personally or by providing direction. The use of experts alone could potentially concentrate responsibility for dementia care in a small staff group rather than create a culture where all staff are responsible. Evidence from one paper [50] suggested that even when ward staff as a whole were better able to work with people living with dementia, they would defer issues unrelated to physical or medical healthcare to dementia experts.

*CMOC 4. Staff with confidence to adapt working practices and routines to individualise care*

The ability of staff to organise their work around the needs of people living with dementia rather than being restricted to the ward routine was linked to the provision of person-centred care [50, 55, 61, 62, 65, 69]. Where staff could incorporate getting to know the person, or recognise and respond directly to expressions of distress and unmet needs, patient wellbeing reportedly improved, evidenced through observations of positive mood [55, 61, 62, 65]. Clarity in staffs' responsibility for patient care was an important resource for improving their autonomy and encouraging them respond in timely, creative ways to meet individual needs [55, 61, 62].

Flexibility in working practices was suggested to be a factor in improving functional outcomes for people living with dementia. One study [69] attributed gains in mobility after hip surgery to therapy staff using their professional judgement to recognise optimal times that a person living with dementia would engage with a psychotherapy session, rather than risk the session being rejected. Additional factors that supported therapy staff to work flexibly included training in dementia care, reduced patient lists, and treatment rooms located on the ward [73].

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*CMOC 5. Staff with responsibility to focus on psychosocial needs*

Time constraints and staffing resources limited staff capacity to provide good dementia care. This was often addressed by employing staff with a specific role prioritising psychological, emotional and social needs through the use of cognitive and psychosocial assessments, therapeutic activities, supervising mealtimes, and managing risk [10, 50, 52, 54, 62, 65, 68]. The use of these staff and the activities they provided improved patient experience [62], assisted orientation to time and place [65], reduced distress [50, 62, 65], and reduced the onset of behaviours that challenged staff [50]. Studies reported how activities were sometimes deliberately scheduled to cover known times of high need within the patient population, such as during the afternoon when 'sun-downing' might occur [54] or when staffing levels were stretched, such as during mealtimes. For example, activities co-ordinators offered social dining opportunities where they could support conversations and prompt patients to eat [50, 62, 65, 70]. Although studies reported improved nutritional intake this was not formally evaluated.

Patients with more severe physical illness or cognitive impairment may not be able to participate in activities [50, 52] although it is possible they may have benefited indirectly as healthcare staff had more time to address their physical and medical needs. While this was referred to in two of the interviews, this was not explored in any of the papers.

Ward-wide staffing levels and skill mix impacted on staff ability to prioritise emotional, psychological and social needs [50, 62]. At times of staff shortages, ward management prioritised safety and managing risk over other non-medical needs [50, 62]. Risk management techniques, such as the use of 'specials' could be applied in a way that also addressed psychosocial needs. Two studies [50, 62] described how staff allocated to monitor patients at risk of falls engaged the patients in games, activities, and conversations. However, this was not always the case as staff assigned as 'specials' were often junior team members, had not received training in dementia care, and were unclear of the purpose of the role beyond monitoring the patient. This resulted in a lack of interaction with the patient and increased patient distress [68].

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*CMOC 6 Building staff confidence to provide person-centred risk management*

We found evidence that addressing risk in a way that supported a person's abilities, choices and independence improved mobility [54, 64], reduced adverse incidents [70], and improved patient and carer satisfaction [50, 53, 67]. Training, for example, on new skills and procedures for managing risk from change agents with clinical expertise and organisational authority, ensured staff understood the benefits to patients and had confidence to implement approved working practices [54, 67, 71]. Structural factors influenced the way risk was addressed. For example wards with locked door access meant patients could be monitored from a distance without restricting their movement around the ward [50, 53, 54, 66]; potentially leading to a reduction in behaviours that challenge as 'wandering' behaviours were no longer considered problematic.

In open wards, alternative methods were developed to easily identify patients considered at risk of leaving the ward, such as the use of wrist bands and different coloured hospital clothing, allowing staff to monitor them from a distance and intervene as necessary [10, 59, 64]. Identification methods were supported by staff training in the appropriate way to encourage a patient to return to their ward [10, 64].

**Refined programme theory**

From data in phase one we hypothesised that the existence of a change agent was important for improving hospital care for people living with dementia. However, work in phase two suggested that a reliance on single initiatives, such as a change agent, was insufficient to change staff behaviour. Additional contextual factors were also necessary in order for staff to make use of the resources interventions provided and use them in their practice with people living with dementia. The six context-mechanism-outcome configurations have been incorporated into a refined programme theory to suggest what needs to be in place to encourage best practice for dementia care in hospitals (figure 2). Figure 2 presents the programme theory. The preliminary CMOC suggests that resources which promote dementia awareness and an understanding of what constitutes 'good' dementia care are often initially implemented in situations where staff have limited understanding of how to provide care that addresses the needs of people living with dementia. These resources support staff to recognise the benefit of working well with patients with dementia and provides them with a common understanding of what good care looks like. This preliminary outcome then becomes part of the new context. Contextual factors, such as organisational endorsement of dementia care practices and clarity in staff

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responsibilities to patients with dementia, encourage staff to value resources, reinforcing improvements to care provision. It is anticipated that this will lead to improved patient outcomes, though evidence on outcomes was limited.

## DISCUSSION

Our review demonstrates how consideration of different contextual components in hospitals, hospital staff, and patients was fundamental to how the resources of an intervention might influence staff reasoning to adopt good dementia care practices. These changes in care practices may then lead to improved healthcare outcomes for people living with dementia. Developing an understanding in staff of the difficulties dementia presents for people with the condition helped them to recognise the need to approach care differently. Previous reviews of dementia care in hospital settings have identified training as an important strategy to improve staff knowledge of dementia and confidence to work well with people living with dementia, but have provided limited evidence for how this effects patient outcomes [29, 74, 75]. Findings from this review would suggest that training as a single strategy is not enough to influence staff to adapt the care they provide for people living with dementia. The culture of care within an organisation needs to support staff to provide good care for people living with dementia, legitimising practices so they are valued by staff. This means organisations need to recognise the impact this has on staff workload and roles and the changes that are necessary to ensure care provision can be adaptive to the needs of the patient. Staff needed to have a clear understanding of the expectation for care standards, and be confident that these changes are accepted by colleagues and senior staff if they are to improve the way care is provided for people living with dementia. Managerial endorsement for staff to work flexibly within their role, utilising practices and resources that enable them to get to know the person, will help staff to recognise and address signs of distress and implement best practice in dementia care.

Turner, et al. [74] suggests that to achieve the type of culture where person-centred care is valued, training in dementia should be aimed at a managerial level. Findings from this review would support their opinion; included studies where change agents in senior positions understood dementia and the associated impact on patient experience and care of the patient were reportedly able to positively influence the culture of care [53-55, 59, 63, 70, 72]. They communicated their vision for good dementia care, addressed processes within and between departments, provided resources that supported staffs' work, and considered the impact of changes to roles and responsibilities. However, even with this endorsement, there were still times, such as concerns for managing risk and resource shortages, where staff responsibilities were reorganised to prioritise physical over psychological wellbeing.

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Limited time and resources, and a preoccupation with managing risk are commonly cited factors that impacted on the ability of staff and organisations to sustain dementia-friendly hospital environments [29, 68, 74, 76, 77]. Employing staff who have a responsibility for the psychosocial needs of the patient can potentially improve patient experience of care while also making time available for nursing and medical staff to focus on physical and medical care needs of the patient. However, it is essential that contextual factors, such as staff awareness in dementia and dementia care, and staff clarification of their role and responsibilities are addressed before staffing resources are implemented into the setting. Moyle, et al. [68] demonstrated how the use of 'specials' without training in dementia care, a clear understanding of their role, and a prioritisation of risk management over addressing psychosocial needs resulted in poor outcomes for patients, such as increased agitation and reduced autonomy. A review on special observation [78] underlined the importance of clarity in the purpose of the role and adequately trained staff to optimise the role's therapeutic potential. Where responsibilities for care are assigned solely by the patient's symptoms this can lead to a narrow reactive approach to dementia care. Staff will still need to work as a team, rather than creating new tasks to focus on.

The initial aim of the review was to develop, test and refine a programme theory for how dementia-friendly interventions influence outcomes for people living with dementia during hospital admissions. However, testing the theory was problematic; evidence was limited, much was descriptive, there were few evaluations of interventions and approaches, and limited descriptions of setting and component parts of the interventions which impacted on the development of CMOC. Moreover, most studies included in the review reported little information around patient characteristics (e.g. type and severity of dementia) which meant we were unable to establish how the characteristics of people living with dementia interacted with the components of the interventions to influence outcomes.

Available evidence clustered around the training for staff and organisational support for changes to care practices. There was less evidence for how the introduction of staff providing activity and therapy for people living with dementia impacted on the practices of other staff. This review does, however, provide a programme theory that can be used as the basis for future evaluations. Our review also highlights the importance of focusing on patient related outcomes. It was clear from the initial interviews that whilst there was a shared understanding of the importance of dementia-friendly care, less attention has been paid to how different approaches enhanced patient outcomes. By focusing on outcomes as the

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basis for inclusion, this review addresses a knowledge gap about how different resources and approaches for dementia-friendly healthcare are effective for patients.

## CONCLUSION

The programme theory that has emerged from this review has the potential to improve how interventions to support dementia-friendly care in hospitals are designed and evaluated. The review highlights what needs to be in place to maximise the impact of training and the key characteristics for staff acting as change agents to influence colleagues to practice good dementia care. Specifically, the elements of interventions need to be relevant to provide ward staff with the awareness, authority, and resources to provide personalised care with support from staff with the relevant expertise. Educational interventions should focus on how staff can identify with the experience of being a patient living with dementia, combined with opportunities for staff to share their experiences of addressing challenges linked with the impact of dementia related behaviours on ward routines and priorities. This review provides a timely contribution and challenges the assumption that dementia awareness initiatives in acute care settings alone are sufficient to improve patient care.

## CONTRIBUTORS

MH led the design and prepared the review as part of her PhD (University of Hertfordshire, Hertfordshire, UK) and led manuscript preparation. FB and CG wrote the original funding application, supervised the review development, and critically reviewed manuscript drafts. All authors contributed to the debate and interpretation of data, read, and approved the final manuscript.

## AVAILABILITY OF DATA AND MATERIAL

All evidence cited in this review is available in the public domain. Data from the stakeholder interviews are not available to protect individuals' anonymity.

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## DISCLAIMER

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the paper.

## COMPETING INTERESTS

The authors declare that they have no competing interests.

## ETHICS APPROVAL

Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

## CONSENT FOR PUBLICATION

Participants in stakeholder interviews consented to participation and the use of anonymised interview excerpts.

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## REFERENCES


1. Alzheimer's Society. Fix Dementia Care: Hospitals. London: Alzheimer's Society, 2016.
2. Alzheimer's Society. Counting the cost: Caring for people with dementia on hospital wards: Alzheimer's Society London, 2009.
3. Poblador-Plou BC-L, Amaia; Marta-Moreno, Javier; Hancco-Saavedra, Jorge; Sicras-Mainar, Antoni; Soljak, Michael; Prados-Torres, Alexandra. Comorbidity of dementia: a cross-sectional study of primary care older patients. *BMC psychiatry* 2014;**14**(1):84
4. Bunn FB, Ann-Marie; Goodman, Claire; Rait, Greta; Norton, Sam; Robinson, Louise; Schoeman, Johan; Brayne, Carol. Comorbidity and dementia: a scoping review of the literature. *BMC medicine* 2014;**12**(1):192
5. Royal College of Psychiatrists. Report of the national audit of dementia care in general hospitals 2011: Healthcare Improvement Quality Partnership, 2013.
6. Bunn F, Dickinson A, Simpson C, et al. Preventing falls among older people with mental health problems: a systematic review. *BMC nursing* 2014;**13**(1):4
7. Orsitto G, Fulvio F, Tria D, Turi V, Venezia A, Manca C. Nutritional status in hospitalized elderly patients with mild cognitive impairment. *Clinical Nutrition* 2009;**28**(1):100-02
8. Bail K, Goss J, Draper B, Berry H, Karmel R, Gibson D. The cost of hospital-acquired complications for older people with and without dementia; a retrospective cohort study. *BMC health services research* 2015;**15**(1):91
9. Elvish RB, Simon; Cawley, Rosanne; Harney, Kathryn; Graham, Pat; Pilling, Mark; Gregory, Julie; Roach, Pamela; Fossey, Jane; Keady, John. 'Getting to Know Me': the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & mental health* 2014;**18**(4):481-88
10. Galvin JEK, Barbara; Al-Hammadi, Noor; Germino, Jessica; Murphy-White, Maggie; McGillick, Janis. "Dementia-friendly hospitals: care not crisis" An educational program designed to improve the care of the hospitalized patient with dementia. *Alzheimer disease and associated disorders* 2010;**24**(4):372
11. Bunn F, Goodman C, Brayne C, et al. Comorbidity and dementia: improving healthcare for people with dementia. www. nets.nihr. ac. uk/projects/hsdr/11101707. NIHR, HS & DR, 2012.
12. White N, Leurent B, Lord K, Scott S, Jones L, Sampson EL. The management of behavioural and psychological symptoms of dementia in the acute general medical hospital: a longitudinal cohort study. *International Journal of Geriatric Psychiatry* 2016
13. Benbow SMJ, David. Dementia: stigma and its effects. *Neurodegenerative Disease Management* 2012;**2**(2):165-72
14. Swaffer K. Dementia: Stigma, Language, and Dementia-friendly. *Dementia* 2014;**13**(6):709-16 doi: 10.1177/1471301214548143published Online First: Epub Date]|.
15. Waller S, Masterson A. Designing dementia-friendly hospital environments. *Future Hospital Journal* 2015;**2**(1):63-68
16. Department of Health. Living Well with Dementia: a national dementia strategy. In: Health Do, ed. London, 2009.
17. Department of Health. Prime Minister's challenge on dementia 2020. In: Health Do, ed. London, 2015.
18. Health Education England. Dementia: Improving dementia care through effective basic training and continuous professional and vocational development. Secondary Dementia: Improving dementia care through effective basic training and continuous professional and vocational development 2016. https://www.hee.nhs.uk/our-work/hospitals-primary-community-care/mental-health-learning-disability/mental-health/dementia.
19. World Health Organization. Global age-friendly cities: A guide: World Health Organization, 2007.


For peer review only

20. Crampton J, Dean, J., Eley, R., AESOP Consortium. Creating a dementia-friendly York: Joseph Rowntree Foundation York, 2012.
21. Mitchell L, Burton E, Raman S. Dementia-friendly cities: Designing intelligible neighbourhoods for life. *Journal of Urban Design* 2004;**9**(1):89-101 doi: 10.1080/1357480042000187721published Online First: Epub Date]|.
22. Mitchell L, Burton E. Designing dementia-friendly neighbourhoods: helping people with dementia to get out and about. *Journal of Integrated Care* 2010;**18**(6):11-18
23. https://www.dementiafriends.org.uk/. Dementia Friends. Secondary Dementia Friends.
24. Joseph Rowntree Foundation. Developing a national user movement for people with dementia - learning from the Dementia Engagement and Empowerment Project (DEEP). 2015
25. Royal College of Nursing. Dementia: Commitment to the care of people with dementia in hospital settings. London, 2013.
26. Department of Health. Prime Minister's challenge on dementia: Delivering major improvements in dementia care and research by 2015. In: Health Do, ed. London, 2012.
27. Mayrhofer AG, C.; Holman, C. Establishing a community of practice for dementia champions (innovative practice). *Dementia (London, England)* 2014 doi: 10.1177/1471301214542534published Online First: Epub Date]|.
28. Mayrhofer A, Goodman C, Sharpe R, Dye H. Dementia Education in Hertfordshire and Bedfordshire: An organisational audit commissioned by Health Education East of England. Centre for Research in Primary and Community Care (CRIPACC), University of Hertfordshire. Hatfield: University of Hertfordshire, 2014.
29. Dewing JD, Saskia. What is the current state of care for older people with dementia in general hospitals? A literature review. *Dementia* 2014:1471301213520172
30. Pawson R. Evidence-based policy: A realist perspective: Sage publications, 2006.
31. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC medicine* 2013;**11**(1):21
32. Dalkin SM, Greenhalgh J, Jones D, Cunningham B, Lhussier M. What's in a mechanism? Development of a key concept in realist evaluation. *Implementation Science* 2015;**10**(1):49
33. Pawson and Tilley. Realistic evaluation: Sage, 1997.
34. Handley M, Bunn F, Goodman C. Interventions that support the creation of dementia friendly environments in health care: protocol for a realist review. *Systematic reviews* 2015;**4**(1):1
35. Spencer; Ra. Qualitative data analysis for applied policy research. *The qualitative researcher's companion* 2002:305-29
36. Kitwood T, Bredin K. Evaluating dementia care the DCM method: Bradford, England: Bradford Dementia Research Group, Bradford University, 1997.
37. Wong G, Greenhalgh T, Pawson R. Internet-based medical education: a realist review of what works, for whom and in what circumstances. *BMC medical education* 2010;**10**(1):12
38. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review–a new method of systematic review designed for complex policy interventions. *Journal of health services research & policy* 2005;**10**(suppl 1):21-34
39. Williams R. Hospital programme for dementia-specific care: Using detailed observations of patients' experiences, Barbara Hodkinson developed the Butterfly Scheme to identify people with memory impairment and improve their care. She tells Ruth Williams how it works. *Nursing older people* 2011;**23**(7):14-17
40. Banks PW, A.; Henderson, J.; Sharp, B.; Brown, M.; Oliver, J.; Marland, G. Enriching the care of patients with dementia in acute settings? The Dementia Champions Programme in Scotland. *Dementia (London, England)* 2014;**13**(6):717-36 doi: 10.1177/1471301213485084published Online First: Epub Date]|.
41. Crabtree J, Mack J. Developing champions to enhance the care of people with dementia in general hospitals. *Nursing times* 2010;**106**(48):13-14

For peer review only

42. Ellison S, Watt G, Christie I. Evaluating the impact of the Alzheimer Scotland Dementia Nurse Consultants/Specialists & Dementia Champions in bringing about improvements to dementia care in acute general hospitals. 2014
43. Waugh AM, G.; Henderson, J.; Robertson, J.; Wilson, A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-9 doi: 10.7748/ns2011.04.25.32.44.c8452published Online First: Epub Date]|.
44. Wilkinson I, Coates A, Merrick S, Lee C. Junior doctor dementia champions in a district general hospital (innovative practice). *Dementia (London, England)* 2015 doi: 10.1177/1471301215584083published Online First: Epub Date]|.
45. Elliot R, Adams J. The creation of a Dementia Nurse Specialist role in an acute general hospital. *Journal of psychiatric and mental health nursing* 2011;**18**(7):648-52 doi: 10.1111/j.1365-2850.2011.01771.xpublished Online First: Epub Date]|.
46. Griffiths P, Bridges J, Sheldon H, Thompson R. The role of the dementia specialist nurse in acute care: a scoping review. *Journal of clinical nursing* 2014
47. Holmes J, Montaňa C, Powell G, et al. Liaison Mental Health Services for Older People: A Literature review, service mapping and in-depth evaluation of service models. *Produced for the National Institute for Health Research Service Delivery and Organisation programme* 2010
48. Baldwin R, Pratt H, Goring H, Marriott A, Roberts C. Does a nurse-led mental health liaison service for older people reduce psychiatric morbidity in acute general medical wards? A randomised controlled trial. *Age and ageing* 2004;**33**(5):472-78
49. Waller S. Redesigning wards to support people with dementia in hospital: Sarah Waller describes a programme that is bringing staff and patients together to create more welcoming and inspiring therapeutic environments. *Nursing older people* 2012;**24**(2):16-21
50. Goldberg S, Whittamore KH, Pollock K, Harwood RH, Gladman JR. Caring for cognitively impaired older patients in the general hospital: a qualitative analysis of similarities and differences between a specialist Medical and Mental Health Unit and standard care wards. *Int J Nurs Stud* 2014;**51**(10):1332-43 doi: 10.1016/j.ijnurstu.2014.02.002published Online First: Epub Date]|.
51. Goldberg S, Bradshaw, Lucy E; Kearney, Fiona C; Russell, Catherine; Whittamore, Kathy H; Foster, Pippa ER; Mamza, Jil; Gladman, John RF; Jones, Rob G; Lewis, Sarah A. Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial). *BMJ (Clinical research ed.)* 2013;**347**
52. Spencer K, Foster, P., Whittamore, K. H., Goldberg, S. E., Harwood, R. H. Delivering dementia care differently--evaluating the differences and similarities between a specialist medical and mental health unit and standard acute care wards: a qualitative study of family carers' perceptions of quality of care. *BMJ open* 2013;**3**(12):e004198 doi: 10.1136/bmjopen-2013-004198published Online First: Epub Date]|.
53. Nichols JN, Heller KS. Windows to the heart: Creating an acute care dementia unit. *Journal of palliative medicine* 2002;**5**(1):181-92
54. Zieschang T, Dutzi I, Müller E, et al. Improving care for patients with dementia hospitalized for acute somatic illness in a specialized care unit: a feasibility study. *International Psychogeriatrics* 2010;**22**(01):139-46
55. Scerri A, Innes A, Scerri C. Discovering what works well: exploring quality dementia care in hospital wards using an appreciative inquiry approach. *Journal of clinical nursing* 2015
56. Waugh A, Marland G, Henderson J, Robertson J, Wilson A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-49

For peer review only

57. Mayrhofer A, Goodman C, Holman C. Establishing a community of practice for dementia champions (innovative practice). *Dementia* 2015;**14** doi: 10.1177/1471301214542534published Online First: Epub Date]|.
58. Griffiths A, Knight A, Harwood R, Gladman JR. Preparation to care for confused older patients in general hospitals: a study of UK health professionals. *Age and ageing* 2013:aft171
59. Baillie L. An Evaluation of Barbara's Story: Final Report. London: Guy's and St Thomas' NHS Foundation Trust, London South Bank University, 2015.
60. Dowding D, Lichtner V, Allcock N, et al. Using sense-making theory to aid understanding of the recognition, assessment and management of pain in patients with dementia in acute hospital settings. *International Journal of Nursing Studies* 2016;**53**:152-62
61. Schneider J, Scales K, Bailey S, Lloyd J. Challenging care: the role and experience of health care assistants in dementia wards. *National Institute for Health Research Service Delivery and Organisation programme. Available online at http://panicoa. org. uk/sites/assets/challenging_care. pdf [Accessed August]* 2010
62. Bray J, Evans S, Bruce M, et al. Improving activity and engagement for patients with dementia. *Nursing older people* 2015;**27**(8):22
63. Brooker DM, Sarah; Evans, Simon; Carter, Christine; Bruce, Mary; Thompson, Rachel. RCN Development Programme: Transforming Dementia Care in Hospitals Evaluation Report. 2014
64. Duffin C. Raising awareness to support people with dementia in hospital: A film produced to train staff at one trust has had such a positive effect that it is to be used nationwide. Christian Duffin reports on this and other measures to improve care. *Nursing older people* 2013;**25**(5):14-17
65. Edvardsson D, Sandman PO, Rasmussen B. Forecasting the ward climate: a study from a dementia care unit. *Journal of clinical nursing* 2012;**21**(7-8):1136-114
66. Gonski PN, Moon I. Outcomes of a behavioral unit in an acute aged care service. *Archives of gerontology and geriatrics* 2012;**55**(1):60-65
67. Luxford K, Axam A, Hasnip F, et al. Improving clinician–carer communication for safer hospital care: a study of the 'TOP 5'strategy in patients with dementia. *International Journal for Quality in Health Care* 2015:mzv026
68. Moyle W, Borbasi S, Wallis M, Olorenshaw R, Gracia N. Acute care management of older people with dementia: a qualitative perspective. *Journal of clinical nursing* 2011;**20**(3-4):420-28
69. Rösler A, von Renteln-Kruse W, Mühlhan C, Frilling B. Treatment of dementia patients with fracture of the proximal femur in a specialized geriatric care unit compared to conventional geriatric care. *Zeitschrift für Gerontologie und Geriatrie* 2012;**45**(5):400-03
70. Upton. An evaluation of quality and cost effectiveness of a newly defined suite of care interventions for patients with dementia and their carers in the acute hospital setting developed by The Royal Wolverhampton Hospitals NHS Trust REPORT PHASE 2 – Volume 1: University of Worcester, 2012.
71. Enns E, Rhemtulla R, Ewa V, Fruetel K, Holroyd-Leduc JM. A controlled quality improvement trial to reduce the use of physical restraints in older hospitalized adults. *Journal of the American Geriatrics Society* 2014;**62**(3):541-45 doi: 10.1111/jgs.12710published Online First: Epub Date]|.
72. Harwood RH PD, King N, Edwards G, Hammond S, Howe L, et al. . Development of a Specialist Medical and Mental Health Unit for Older People in an Acute General Hospital. MedicalCrises in Older People Discussion Paper Series. Issue 5, November 2010., 2010.
73. von Renteln-Kruse W, Neumann L, Klugmann B, et al. Geriatric Patients With Cognitive Impairment: Patient Characteristics and Treatment Results on a Specialized Ward. *Deutsches Ärzteblatt International* 2015;**112**(7):103
74. Turner A, Eccles FJ, Elvish R, Simpson J, Keady J. The experience of caring for patients with dementia within a general hospital setting: a meta-synthesis of the qualitative literature. *Aging & mental health* 2015:1-11

For peer review only

75. Digby R, Lee S, Williams A. Interviewing people with dementia in hospital: recommendations for researchers. *Journal of clinical nursing* 2016
76. Digby R, Lee S, Williams A. The experience of people with dementia and nurses in hospital: an integrative review. *Journal of clinical nursing* 2016
77. Borbasi S, Jones J, Lockwood C, Emden C. Health Professionals' Perspectives of Providing Care to People with Dementia in the Acute Setting: Toward Better Practice. *Geriatric Nursing* 2006;**27**(5):300-08 doi: 10.1016/j.gerinurse.2006.08.013published Online First: Epub Date]|.
78. Dewing J. Special observation and older persons with dementia/delirium: a disappointing literature review. *International journal of older people nursing* 2013;**8**(1):19-28

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Figure legends

Figure 1: Flow diagram of searches and evidence retrieval

Figure 2: Refined programme theory: CMOC for best practice for care of people living with dementia admitted to hospital

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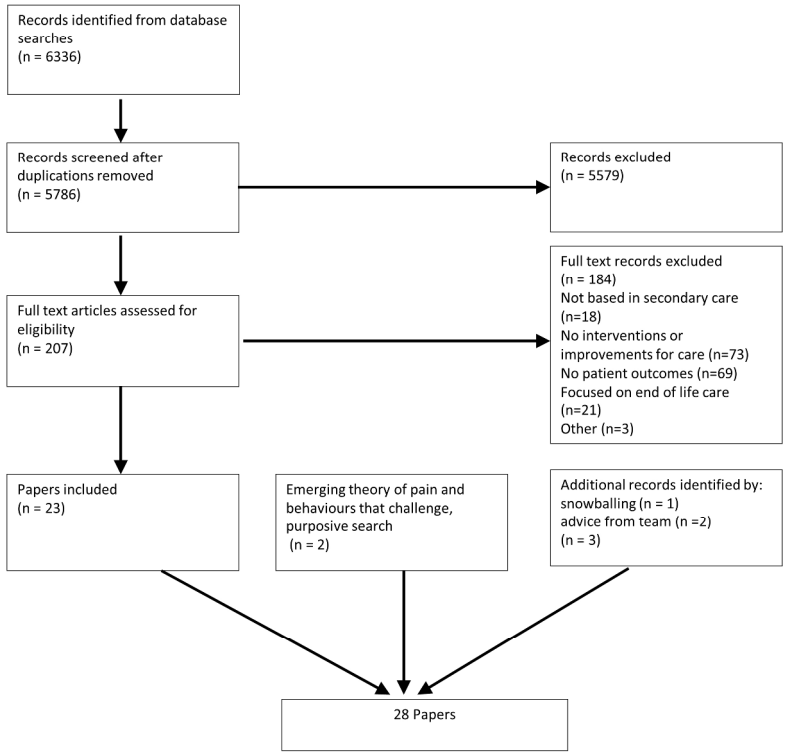


Figure 1: Flow diagram of searches and evidence retrieval

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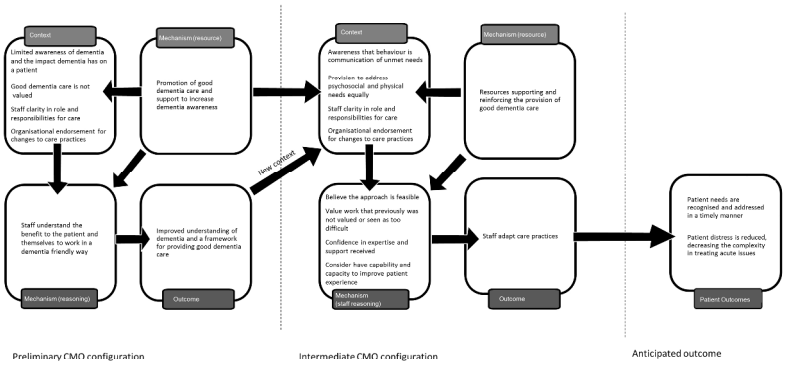


Figure 2: Refined programme theory: CMO configurations for best practice for care of people living with dementia admitted to hospital

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# RAMESES publication standards: realist syntheses

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## Abstract

**Background:** There is growing interest in realist synthesis as an alternative systematic review method. This approach offers the potential to expand the knowledge base in policy-relevant areas - for example, by explaining the success, failure or mixed fortunes of complex interventions. No previous publication standards exist for reporting realist syntheses. This standard was developed as part of the RAMESES (Realist And MEta-narrative Evidence Syntheses: Evolving Standards) project. The project's aim is to produce preliminary publication standards for realist systematic reviews.

**Methods:** We (a) collated and summarized existing literature on the principles of good practice in realist syntheses; (b) considered the extent to which these principles had been followed by published syntheses, thereby identifying how rigor may be lost and how existing methods could be improved; (c) used a three-round online Delphi method with an interdisciplinary panel of national and international experts in evidence synthesis, realist research, policy and/or publishing to produce and iteratively refine a draft set of methodological steps and publication standards; (d) provided real-time support to ongoing realist syntheses and the open-access RAMESES online discussion list so as to capture problems and questions as they arose; and (e) synthesized expert input, evidence syntheses and real-time problem analysis into a definitive set of standards.

**Results:** We identified 35 published realist syntheses, provided real-time support to 9 on-going syntheses and captured questions raised in the RAMESES discussion list. Through analysis and discussion within the project team, we summarized the published literature and common questions and challenges into briefing materials for the Delphi panel, comprising 37 members. Within three rounds this panel had reached consensus on 19 key publication standards, with an overall response rate of 91%.

**Conclusion:** This project used multiple sources to develop and draw together evidence and expertise in realist synthesis. For each item we have included an explanation for why it is important and guidance on how it might be reported. Realist synthesis is a relatively new method for evidence synthesis and as experience and methodological developments occur, we anticipate that these standards will evolve to reflect further methodological developments. We hope that these standards will act as a resource that will contribute to improving the reporting of realist syntheses.

To encourage dissemination of the RAMESES publication standards, this article is co-published in the Journal of Advanced Nursing and is freely accessible on Wiley Online Library (http://www.wileyonlinelibrary.com/journal/jan).

Please see related article http://www.biomedcentral.com/1741-7015/11/20 and http://www.biomedcentral.com/1741-7015/11/22

**Keywords:** realist synthesis, realist review, publication standards

## Background

Academics and policymakers are increasingly interested in 'policy-friendly' approaches to evidence synthesis. Such approaches seek to illuminate issues and understand contextual influences on whether, why and how interventions might work [1,2]. A number of different approaches have been used to try to achieve this goal. At present there is lack of clarity on which methods are best suited for which questions or problems and this has been the subject of debate [3-6] and further research [7]. Realist synthesis is a theory-driven approach that is becoming increasingly popular.

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### What is a realist synthesis?

In this section we briefly describe the realist synthesis method. The realist research question is often summarized as "What works for whom under what circumstances, how and why?" Realist inquiry is based on a realist philosophy of science and considers the interaction between context, mechanism and outcome. From a realist perspective, intervention X is not thought of as having effect size Y with confidence interval Z. Rather, intervention X (for example, a program introduced by policymakers who seek to create a particular outcome) alters context (for example, by making new resources available), which then triggers mechanism(s), which produce both intended and unintended outcomes. Intervention X may work well in one context but poorly or not at all in another context.

Realist inquiry seeks to unpack the context - mechanism - outcome relationship, thereby explaining examples of success, failure and various eventualities in between. Theoretical explanations of this kind are referred to as "middle-range theories" (that is, ones which "...involve abstraction... but [are] close enough to observed data to be incorporated in propositions that permit empirical testing" [8].

The basis of realist inquiry is a realist philosophy, whose key tenets are as follows:

1. There is a [social] reality that cannot be measured directly (because it is processed through our brains, language, culture and so on), but can be known indirectly.

Realism thus sits, broadly speaking, between positivism ('there is a real world which we can apprehend directly through observation') and constructivism ('given that all we can know has been interpreted through human senses and the human brain, we cannot know for sure what the nature of reality is').

2. Social programs (including complex interventions) may change the macro social context (for example, by introducing legislation). They may also change the resources or opportunities available to participants and, in that sense, change the meso- or micro-level context for those participants.

3. To understand the relationship between context and outcome, realism uses the concept of mechanisms, one definition of which is "...underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest" [9].

In common with other theory-driven review methods, the realist approach offers the potential for insights that go beyond the narrowly experimental paradigm of the randomized controlled trial [10-12]. It can do so in relation to complex, complicated or simpler interventions (for example, even a simple intervention, such as a drug, is prescribed, dispensed and taken - or not - in a particular social, cultural and economic context).

"Realist synthesis" was first described by Ray Pawson in 2002 [13], updated in an ESRC (Economic and Social Research Council) commissioned monograph in 2004 [14], published as a book in 2006 [1] and summarizsed in a short methods paper in 2005 [15]. Since this paper is deliberately focused on publication standards, we strongly recommend that those unfamiliar with the realist approach consult these or other relevant methodological sources.

A realist synthesis (or realist review - these terms are synonymous) applies realist philosophy to the synthesis of findings from primary studies that have a bearing on a single research question or set of questions. Methodologically, reviewers may begin by eliciting from the literature the main ideas that went into the making of a class of interventions (the program theory). This program theory sets out how and why a class of intervention is thought to 'work' to generate the outcome(s) of interest. The pertinence and effectiveness of each constituent idea is then tested using relevant evidence (qualitative, quantitative, comparative, administrative and so on) from the primary literature on that class of programs. In this testing, the ideas within a program theory are re-cast and conceptualized in realist terms.

For each idea, reviewers seek out the contextual (C) influences that are hypothesized to have triggered the relevant mechanism(s) (M) to generate the outcome(s) (O) of interest. Synthesis consists of comparing 'how the programme was supposed to operate' to the 'empirical evidence on the actuality in different situations' - all along C-M-O lines. Analytic purchase comes from the ability to describe and understand the many contingencies that affect the likelihood of such interventions generating their intended outcomes. This in turn provides guidance about what policy makers or practitioners might put in place to change the context or provide resources in such a way as to most likely trigger the right mechanism(s) to produce the desired outcome.

### Why are publication standards needed?

Publication standards are common (and, increasingly, expected) - in health services research - see, for example, CONSORT for randomized controlled trials [16], AGREE for clinical guidelines [17], PRISMA for Cochrane-style systematic reviews [18] and SQUIRE for quality improvement studies [19]. For realist syntheses, publication standards are particularly important as this method is relatively new and concerns have been expressed about the rigor with which some realist reviews have been carried out and reported [20]. Publication standards are needed to ensure that users of reviews are provided with relevant and necessary information to enable them to assess the quality and rigor of a review.

In our experience, there is considerable confusion among researchers, journal editors, peer reviewers and

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funders about what counts as a high quality realist review and what, conversely, counts as a flawed review. Even though experts still differ on detailed conceptual methodological issues, the increasing popularity of this method prompted a study to develop baseline standards from which, we anticipate, further developments in theory and methodology of this approach will occur.

## Aim

The aim of this paper is to produce preliminary publication standards for realist syntheses.

## Methods

The methods we used to develop these reporting standards have already been published [20]. In brief, we purposively recruited an international group of experts to our online Delphi panel. Aiming to achieve maximum variety in the relevant sectors, disciplines and expert perspectives represented, we sought panel members working in realist research, evidence synthesis, publication, reviewer training and health policy. Prior to the start of our Delphi panel, with input from an expert informaticist (JB), we collated and summarized existing literature on the principles of good practice in realist synthesis, created a database of such published syntheses, and built relationships with teams who were undertaking ongoing syntheses. Through discussion within the project team, we considered the extent to which the principles had been followed by published and in-progress reviews, thereby identifying how rigor may be lost and how existing methods could be improved.

Our analysis of existing realist syntheses formed the basis of the briefing materials for the first round of the Delphi panel. In addition, we drew on our collective experience in training and supporting realist syntheses teams and an email discussion list on realist and meta-narrative methodology [21] to further inform the contents of our briefing document. Both the research team and panel members contributed draft items for the publication standards, and these were refined using the online Delphi process as previously described [20]. We ran the Delphi panels between September 2011 and March 2012.

### Description of panel and items

In all, we recruited 37 individuals from 27 organizations in 6 countries. These comprised: researchers in public or population health researchers (8); evidence synthesis (6); health services research (8); international development (2); education (2); and also research methodologists (6), publishing (1), nursing (2) and policy and decision making (2). In round 1, 22 Delphi panel members provided suggestions of items that should be included in the publication standards. In rounds 2 and 3 our panel members were asked to rate each potential item for relevance and clarity. The response rates across all items for rounds 2 and 3 were 93% and 89%, respectively. Consensus was reached within three rounds on both the content and wording of 19 items within the publication standards. Table 1 provides an overview of these items.

### Scope of the publication standards

These publication standards are intended to help researchers, authors, journal editors, and policy and decision makers to know and understand what should be reported in the write-up of a realist synthesis. They are not intended to provide detailed guidance on how to conduct such a synthesis; for this, we direct interested readers to summary articles [15,22] or various publications on methods [1,11,14,23]. This publication standard applies only to realist syntheses. A list of publication guidelines for other review methods can be found on the EQUATOR Network's website [24], but at present none of these relate specifically to realist syntheses. As part of the RAMESES project we are also developing quality standards and training materials for realist syntheses, which will be submitted as a separate publication. Publication standards for meta-narrative reviews (also covered in the RAMESES project) have been addressed in a separate article.

### How to use these publication standards

The layout of this document has drawn on previous methodological publications and, in particular, on the 'Explanations and Elaborations' document of the PRISMA statement [18]. Each item is followed by an example drawn from published reviews and a rationale for its inclusion. The purpose of the example text is to illustrate how an item might be reported in a write up. However, potentially relevant contextual information may have been omitted, so it may be necessary to consult the original paper from which the example text was drawn. The standards set out what might be expected for each item, but authors will still need to exercise judgement about how much information to include. The purpose of the details reported should be to ensure that the description and explanation provided is coherent and plausible, both against the guidance set out within an item and for the overall purpose of the realist synthesis.

While this publication standard is modeled on the PRISMA statement, the items within are not identical. This publication standard, developed to apply only to realist syntheses, has some overlap with the PRISMA statement. Items 1 to 3, 15, 16 and 19 in this statement broadly match the purpose of items 1 to 3, 24, 25 and 27 in the PRISMA statement. For items 4 to 14, while there is some overlap in purpose with some PRISMA statement items, different or additional reporting is needed due to the nature of realist syntheses. Other items (5, 12, 13, 15, 16, 19

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**Table 1 List of items to be included when reporting a realist synthesis**

| | | |
|---|---|---|
| **TITLE** | | |
| 1 | | In the title, identify the document as a realist synthesis or review |
| ABSTRACT | | |
| 2 | | While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice. |
| INTRODUCTION | | |
| 3 | Rationale for review | Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area. |
| 4 | Objectives and focus of review | State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review. |
| METHODS | | |
| 5 | Changes in the review process | Any changes made to the review process that was initially planned should be briefly described and justified. |
| 6 | Rationale for using realist synthesis | Explain why realist synthesis was considered the most appropriate method to use. |
| 7 | Scoping the literature | Describe and justify the initial process of exploratory scoping of the literature. |
| 8 | Searching processes | While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected. |
| 9 | Selection and appraisal of documents | Explain how judgements were made about including and excluding data from documents, and justify these. |
| 10 | Data extraction | Describe and explain which data or information were extracted from the included documents and justify this selection. |
| 11 | Analysis and synthesis processes | Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process. |
| RESULTS | | |
| 12 | Document flow diagram | Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example templates (which are likely to need modification to suit the data) that are provided. |
| 13 | Document characteristics | Provide information on the characteristics of the documents included in the review. |
| 14 | Main findings | Present the key findings with a specific focus on theory building and testing. |
| DISCUSSION | | |
| 15 | Summary of findings | Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s). |
| 16 | Strengths, limitations and future research directions | Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged.<br>The limitations identified may point to areas where further work is needed. |
| 17 | Comparison with existing literature | Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic. |
| 18 | Conclusion and recommendations | List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice. |
| 19 | Funding | Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers. |

and 23) in the PRIMSA statement have no equivalent in the RAMESES publication standards for realist reviews.

The order in which items are reported may vary. Realist syntheses are not 'linear' reviews. Some of the processes that are listed may legitimately take place in parallel or have to be revisited at a later date as a review progresses. As a general rule, if a recommended item is excluded from the write-up of a realist synthesis, a justification should be provided.

### The RAMESES publication standards for realist syntheses

#### *Item 1: Title*

In the title, identify the document as a realist synthesis or review.

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**Example**

"Human resource management interventions to improve health workers' performance in low and middle income countries: a realist review." [25]

**Explanation**

Our background searching has shown that some realist reviews are not flagged as such in the title and may also be inconsistently indexed and, hence, are more difficult to locate during searching. The terms 'realist synthesis' and 'realist review' are both in widespread use. We asked our Delphi panel if they had a preferred term - 'realist synthesis' or 'review'. No consensus was reached by our Delphi panel on whether 'review' or 'synthesis' should be the preferred term, and there seemed no good reason to impose one or other term.

***Item 2: Abstract***

While acknowledging that requirements and house style may differ between journals, abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.

**Example**

***"Background***

Legislation is one of the most powerful weapons for improving population health and is often used by policy and decision makers. Little research exists to guide them as to whether legislation is feasible and/or will succeed. We aimed to produce a coherent and transferable evidence based framework of threats to legislative interventions to assist the decision making process and to test this through the 'case study' of legislation to ban smoking in cars carrying children.

***Methods***

We conceptualised legislative interventions as complex social interventions and so used the realist synthesis method to systematically review the literature for evidence. 99 articles were found through searches on five electronic databases (MEDLINE, HMIC, EMBASE, PsychINFO, Social Policy and Practice) and iterative purposive searching. Our initial searches sought any studies that contained information on smoking in vehicles carrying children. Throughout the review we continued where needed to search for additional studies of any type that would conceptually contribute to helping build and/or test our framework.

***Results***

Our framework identified a series of transferable threats to public health legislation. When applied to smoking bans in vehicles; problem misidentification, public support; opposition; and enforcement issues were particularly prominent threats. Our framework enabled us to understand and explain the nature of each threat and to infer the most likely outcome if such legislation were to be proposed in a jurisdiction where no such ban existed. Specifically, the micro-environment of a vehicle can contain highly hazardous levels of second hand smoke. Public support for such legislation is high amongst smokers and non-smokers and their underlying motivations were very similar - wanting to practice the Millian principle of protecting children from harm. Evidence indicated that the tobacco industry was not likely to oppose legislation and arguments that such a law would be 'unenforceable' were unfounded.

***Conclusion***

It is possible to develop a coherent and transferable evidence based framework of the ideas and assumptions behind the threats to legislative intervention that may assist policy and decision makers to analyse and judge if legislation is feasible and/or likely to succeed." [26]

**Explanation**

Apart from the title, an abstract is the only source of information accessible to searchers unless the full paper is obtained. The information in it must allow reviewers and/or users to decide if the review is relevant to their needs.

**Introduction section**

The following items should be reported in the introduction section.

***Item 3: Rationale for review***

Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.

**Example**

"A number of reviews on the subject have tried to examine evidence to improve the operationalization of interventions by CHWs [community health workers], including for child health. Lehmann *et al.* (Reference x1) and Lewin *et al.* (Reference x1) have reviewed evidence on CHW interventions in LMIC [low-middle income countries] and Haines *et al.* (Reference x1) have particularly so for child health. Lewin *et al.* (Reference x1) found lay health workers to be effective in specific areas in child health, when compared to usual care. Haines *et al.* (Reference x1) highlight the contextual nature of CHW's performance. Both caution that CHW interventions are not the panacea for all that ails the health systems in LMIC and that large scale CHW programmes should be initiated with great caution. Both raise questions about the applicability of findings to different settings and about the conditions under which CHW interventions should be implemented." [27]

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**Explanation**

As with all research, a background section explaining what is already known and what the researchers considered to be the 'knowledge gaps' is a helpful orientation.

***Item 4: Objectives and focus of review***

State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.

**Example**

"The overriding question for the review was: Does moving from high-poverty neighborhoods to lower-poverty neighborhoods improve health? More specifically: What were the key health outcomes? Who experienced these outcomes? What appeared to be the mechanisms and associated context leading to the outcomes? As the review proceeded, it became clear that one of the only relatively consistent and statistically significant positive health outcomes was an improvement in mental health for adult women, children and adolescent girls. In this paper a review of mental health outcomes of MTO [Moving To Opportunity] is presented, along with some insights about the mechanisms and contexts through which the intervention appears to have impacted mental health." [28]

**Explanation**

A realist research question contains some or all of the elements of 'What works, how, why, for whom, to what extent and in what circumstances, in what respect and over what duration?' and applies realist logic to address the question (see Item 11).

Because a realist synthesis may generate a large number of avenues that might be explored and explained, and because resources and timescale are invariably finite, the expectation is that the review must be 'contained' by progressively focusing both its breadth (how wide an area?) and depth (how much detail?). This important process may involve discussion and negotiation with, for example, content experts, funders and/or users. It is typical and legitimate for the synthesis' objectives, question and/or the breadth and depth of the review to evolve as the review progresses. How and why it evolved is usually worth reporting.

**Methods section**

The following items should be reported in the methods section.

***Item 5: Changes in the review process***

Any changes made to the review that was initially planned should be briefly described and justified.

**Example**

"As the review progressed we became aware of various data suitability limitations (see Discussion) and the emergence of two prominent demi-regularities prompted us to narrow our review focus to the two candidate theories discussed below." [29]

**Explanation**

A realist synthesis can (and, in general, should) evolve over the course of the review. For example, changes to the research question or its scope are likely to have an impact on many of the synthesis' subsequent processes. However, this does not mean the synthesis can meander uncontained. An accessible summary of what was originally planned (for example, as described in an initial protocol) and how and why this differed from what was done should be provided as this may assist interpretation.

***Item 6: Rationale for using realist synthesis***

Explain why realist synthesis was considered the most appropriate method to use.

**Example**

"Previous reviews sought to understand PR [participatory research] and provide practical recommendations (References x6) and to assess the value of PR to research goals, health status, and systems change (References x6). Nonetheless, the assessment of outcomes remains weak (Reference x4), partly because the methodologies used have generally failed to embrace the complexity of programs or address mechanisms of change (Reference x1). ...

To handle such complexity, we chose a realist approach (Reference x1) because it provides a rationale and tools for synthesizing complex, difficult-to-interpret evidence from community-based programs." [30]

**Explanation**

Realist synthesis is a theory-driven method that is firmly rooted in a realist philosophy of science. It places particular emphasis on understanding causation (in this case, understanding how programs and policies generate outcomes through human decisions) and how causal mechanisms are shaped and constrained by social context. This makes it particularly suitable for reviews of certain topics and questions - for example, complex social programs that involve human decisions and actions. It also makes realist synthesis *less* suitable than other review methods for certain topics and questions - for example, those which seek primarily to determine the average effect size of a simpler intervention administered in a single or limited range of conditions. In our analysis of 37 published realist syntheses, the most common limitation was inadequate engagement with realist explanatory principles and the implications these have, first, for understanding programs and how they work, and second, for cumulating evidence and explanation.

Some realist syntheses published to date have deliberately adapted the method as first described by Pawson.

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Sometimes, adaptations may be entirely justifiable, but at other times they may indicate a poor grasp of realist methodology. To enable judgement to be made on adaptations, the description and rationale for adaptations should be provided. Such information will allow criticism, debate and counter criticism among review teams and users on the suitability of such adaptations, and may well facilitate methodological development.

***Item 7: Scoping the literature***

Describe and justify the initial process of exploratory scoping of the literature.

**Example**

"To develop our framework on the threats to the programme theory of public health legislation we started out by conducting a rapid review of broad areas of public health legislation (covering everything from gun amnesties to food labelling) trying to uncover what had been the sticking points in legislation and how (if at all) they had been circumvented. This outline review led to the construction of a provisional framework for reviewing the family of legislative interventions (as described in Figure 1). .... . Beginning with this framework and through discussions (and with reference to other interested stakeholders) we focused on a subset of themes that seemed most relevant in respect to the intervention in question. In our case, we deliberately sought input from the NICE officer seconded to our project." [26]

**Explanation**

This step is used to build an understanding of the topic area. For example, this step may be used to identify provisional program theories, the names/titles of programs within scope and key authors in the area. Initial attempts to make sense of a topic area may involve informal 'browsing' of the literature and also consulting with experts and stakeholders.

***Item 8: Searching process***

While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.

**Example**

"...the literature search was iterative and ongoing throughout the project. An initial search was conducted of various academic databases, such as Academic Search Premier, Arts and Humanities Citation Index, Canadian Research Index, as well as through various search engines, such as Prowler, Novanet, Google and Google Scholar. Search terms included: Moving to Opportunity [MTO]; housing intervention; housing mobility; housing health effects; low-

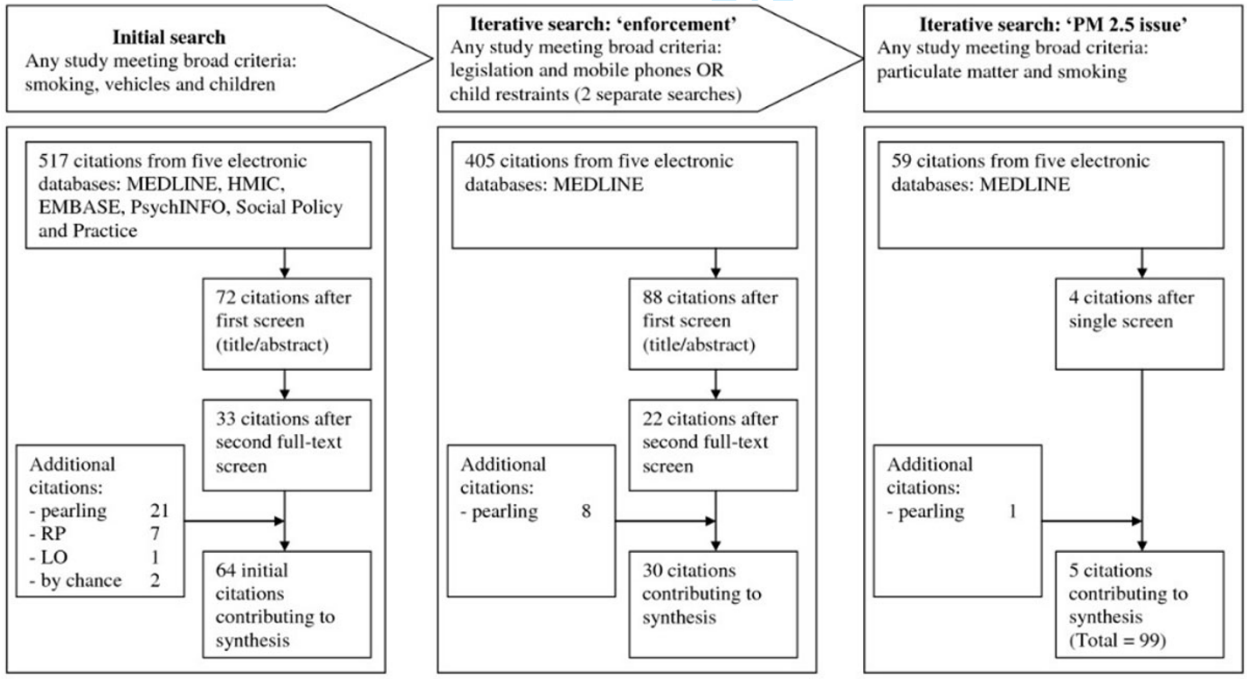


**Figure 1** Flow diagram illustrating search process and article disposition [26].

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poverty neighborhood/community; high-poverty neighborhood/community; neighborhood/community health; poverty neighborhood/community; poverty community effects; poverty housing; poverty health; and housing health. A "snowball" approach was used in which one reference led to others. Other evaluations were revealed through correspondence with Dr. Jeffrey Kling, one of the principal MTO researchers." [28]

**Explanation**

Searching should be guided by the objectives and focus of the synthesis, and revised iteratively in the light of emerging data. Data relevant to a realist synthesis may lie in a broad range of sources that may cross traditional disciplinary, program and sector boundaries. The search phase is thus likely to involve searching for different sorts of data, or studies from different domains, with which to test different aspects of any provisional theory.

Search methods using forward and backward citation tracking may be particularly valuable in finding the documents necessary to develop and then test provisional theories. Realist syntheses do not exclude sources solely on the basis of their study design; hence, 'methodological filters' (for example, to identify randomized controlled trials) may add little to the search and could potentially miss relevant papers.

Searching is likely to be iterative because, as the synthesis progresses, new or refined elements of theory may be required to explain particular findings, or to examine specific aspects of particular processes. As new elements of theory are included, searches for evidence to support, refute or refine those elements may be required. If undertaken, the process used for any such additional searches should be clearly documented. A single pre-defined search is unlikely to be sufficient and may suggest insufficient reflection on emerging findings.

Sufficient detail should be given to enable the reader to judge whether searching was likely to have located sources needed for theory building and/or testing.

***Item 9: Selection and appraisal of documents***

Explain how judgements were made about including and excluding data from documents, and justify these.

**Example**

"Three tools were developed (for identification, selection, and appraisal) in March, June, and October 2009, respectively. Modifications were made during each stage after piloting. Each stage processed a different type of data: citations in identification; full-text papers in selection; and sets of publications in appraisal.

...The identification tool consisted of three questions. This step funnelled the number of citations from 7,167 to 594.

The librarian (JH) retrieved the 594 full-text papers, which were read by two independent reviewers, using a selection tool initially comprised of six questions in June 2009, with an additional two questions added in October 2009. ...

Two hundred articles remained from 594 after filtering them through the selection tool. Due to the complexity of the dataset, we decided at this stage to further limit the scope of our review to community-based settings, and to participatory interventions. Our rationale was that: PR in all forms (community-based PR, organizational PR, action research) was too diverse to be assessed within one review; the complexity of PR benefits from community-based research provided a manageable set of studies; intervention research demonstrated more complexity of outcomes than non-intervention research, and would be best suited for analysis using realist review methods; and the pool of studies needed to be reduced to a manageable size for an in depth realist synthesis (analysis). Adding two questions reduced the pool to 83 studies.....

Contact with principal investigators of all full-text papers retained after selection was undertaken because descriptions of programs, methods and findings of PR interventions were found to be commonly described across a number of publications pertaining to the same intervention. It was thus necessary to confirm that we had complete sets of papers in order to fairly appraise projects according to the realist review approach. ... For each study, we then sent our list of papers to the corresponding author or PI, and asked them to confirm that we had the complete set, or to send us additional documents. ... Only those sets of studies in which the contacted researcher responded to our request were retained for appraisal.

.... The appraisal tool consisted of three questions. An additional 11 sets were eliminated after screening with the tool below, which left a total of 23 sets, comprising 276 documents that were retained for synthesis. See Appendix 4: ... for a complete breakdown of the number of cases retained at each stage." [30]

**Explanation**

Realist synthesis is not a technical process - that is, following a set protocol will not guarantee that a review will be robust. Rather, it requires a series of judgements about the relevance and robustness of particular data for the purposes of answering a specific question.

Within any document, there may be several pieces of data that serve different purposes, such as helping to build one theory, refining another theory and so on. Therefore, the selection (for inclusion or exclusion) and appraisal of the contribution of pieces of data within a document cannot be based on an overall assessment of study or

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document quality. An appraisal of the contribution of any section of data (within a document) should be made on two criteria:

- *Relevance* - whether it can contribute to theory building and/or testing; and
- *Rigor* - whether the method used to generate that particular piece of data is credible and trustworthy.

A wide range of documents can potentially contribute to a realist synthesis. For example, outcome and impact studies, qualitative interviews, ethnography, questionnaire surveys, mixed-method case studies, and close reading of policies, business plans, websites, project initiation documents and 'gray literature' write-ups of programs may all contribute in different ways of identifying and elucidating program theories. Because of this range and realist review's focus on relevance and rigor, it can initially be difficult to 'whittle down' the number of documents that are potentially eligible for inclusion in a review. This process can only occur as the data sources are analyzed in detail. Thus, in practice, the selection and appraisal stage may need to run in parallel with the analysis stage.

It is unlikely that authors will be able to provide an in-depth description of each decision involved, but the broad processes used to determine relevance and assess rigor (for example, using quality standards appropriate to particular kinds of research to appraise documents or sections of documents; discussion and/or debate within a review team of a document's findings; or consulting experts about technical aspects of methods or findings) should be described. While the description of the processes followed will not allow the reader to draw firm conclusions about judgements made, it will give an indication of the coherence, plausibility and appropriateness of the processes used to inform those judgements.

***Item 10: Data extraction***

Describe and explain which data or information were extracted from the included documents and justify this selection.

**Example**

"In order to identify key elements of importance to the success or failure of an intervention in a certain context using a realist perspective, information was gathered on the intervention, the context and the actual "working of the intervention" or the mechanisms. As we intended to discuss the strength of the evidence and the usefulness of the application of realist principles to already published studies, we developed a process of data analysis that was comprehensive and as objective and transparent as possible. Therefore, a data analysis matrix was developed by the team of authors (see Annex 2). During the development of this matrix, the team extensively discussed and defined terms (such as context, mechanisms and outcome) and evaluation levels (such as process, output and outcome)." [31]

**Explanation**

In a realist synthesis, data extraction assists analysis and synthesis. Reporting on what was extracted and why can add to the transparency of the synthesis process.

The extracted data may consist of descriptions (for example, of the detail of what was done in a program), findings (for example, cure rates, mortality) or explanations about how and why the program may have worked in particular contexts. Of particular interest to the realist reviewer are data that support the use of realist logic to answer the review's question(s) - for example, data on context, mechanisms and outcome configurations, demi-regularities, middle-range and/or program theories. Realist synthesis is used for a wide range of research questions, so it is impossible to be prescriptive about what data should be extracted. However, the link between the research question and the category of data extracted should be clear.

***Item 11: Analysis and synthesis processes***

Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.

**Example**

"Data synthesis was undertaken either by RP and/or GW and synthesis results were regularly shared and discussed within the review team to ensure validity and consistency in the inferences made. Specifically (where relevant), we attempted to identify prominent recurrent patterns of contexts and outcomes (demi-regularities) in the data and then sought to explain these through the means (mechanisms) by which they occurred. For example, we noted that in our included articles self-reported public support for a ban on smoking in vehicles carrying children was often found to be high amongst smokers. During data synthesis we would then aim to provide an explanation of this demi-regularity through the identification of mechanism(s). As we delved further into our included articles and beyond (through our aforementioned purposive searching) for an explanation, data emerged that smokers harboured within them the wish to want to protect children from harm and also regret at having started smoking. We interpreted these as (realist) mechanisms and, for the former, were able to find substantive (middle-range) theory in the form of the Millean principle [Reference x1] to explain its interaction with context to influence outcomes. When additional studies were sought to enable programme theory testing, data handling processes .... were repeated." [26]

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**Explanation**

In a realist synthesis, the analysis and synthesis processes occur iteratively and may be sequential or in parallel. At the center of any realist analysis is the application of a realist philosophical 'lens' to data. A realist analysis of data specifically seeks to analyze data using realist concepts. Specifically, realism adheres to a generative explanation for causation - that is, an outcome (O) of interest was generated by relevant mechanism(s) (M) being triggered in context (C). Within or across the included documents, recurrent patterns of outcomes (or demi-regularities) and their associated mechanisms and contexts (CMO configurations) are likely to occur.

During synthesis the goal is to make sense of the analyzed data using theory, at one of two levels. First, theory (or theories) may be sought, developed and/or refined to explain how it is that a program (or part of a program) achieves its outcomes (that is, the mechanism(s) operating within a program) and the contexts in which those mechanisms do and do not fire. This provides a realist program theory. Second, theory (or theories) may be sought, developed and/or refined to explain, at a somewhat more general level, the pattern of contexts, mechanisms and outcomes. A full realist analysis addresses both these levels and attempts to make sense of the relationship between these two levels. Syntheses which address only one level may also be considered realist syntheses assuming that they apply and demonstrate application of a realist philosophy of science. The level(s) of analysis chosen will depend on the review's focus. The theories used may have been developed and/or refined from the data and/or be refinement of existing substantive theory.

The key analytic process in realist review involves iterative testing and refinement of theoretically based explanations using empirical findings in data sources. Reviewers may draw on any appropriate analytic techniques to undertake this testing. Explanation and justification for the choice of techniques should be provided.

Ideally a description should be provided on how all the individuals involved in the review have been involved in the analysis and synthesis processes, and how these evolved as the review took shape.

**Results section**

The following items should be reported in the results section.

***Item 12: Document flow diagram***

Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example provided (which is likely to need modification to suit the data) in Figure 1.

**Example**

"See Figure 1: Flow diagram illustrating search process and article disposition." [26]

**Explanation**

A flow diagram provides an accessible summary of the sequence of steps and gives an indication of the volume of data included and excluded at each step.

***Item 13: Document characteristics***

Provide information on the characteristics of the documents included in the synthesis.

**Example**

"Additional File 1 summarises ..., the context, the intervention, the mechanisms triggered and the reported outcomes. Additional File 1 shows that in all the trials, more than one type of intervention was applied to improve CHWs [community health workers] performance. It also shows that the outcomes are reported not in terms of CHW performance, but rather in terms of the consequences of their performance on specific health outcomes." [27]

**Explanation**

A clear summary of the characteristics of included sources can add to the transparency of the synthesis and some characteristics may help readers judge the coherence and plausibility of inferences. Examples of possibly relevant characteristics of documents that may be worth reporting include, where applicable: full citation, country of origin, study design, summary of key main findings, use made of document in the synthesis and relationship of documents to each other (for example, there may be more than one document reporting on an intervention). While considering specific requirements of any particular publication, reviewers may wish to tabulate key characteristics.

***Item 14: Main findings***

Present the key findings with a specific focus on theory building and testing.

**Example**

"Using this theoretical concept, we hypothesized that equitable partnerships, with the stakeholders' participation throughout the project, succeed largely through synergy. Through the synthesis process using CMO configuring, we refined the theory by demonstrating that synergy is both an outcome and a context for partnership development - so that when synergy generated positive outcomes (e.g., enhanced trust or improved data collection), those outcomes generated new synergy. Expanding this logic, we demonstrated how partnership synergy created momentum over time, producing resilience in the face of obstacles as well as sustaining health-related goals, extending

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Wong et al. BMC Medicine 2013, 11:21
http://www.biomedcentral.com/1741-7015/11/21



programs and infrastructure, and creating new and unexpected ideas and activities." [30]

**Explanation**

The defining feature of a realist synthesis is the nature of the theory(ies) it offers. Such a theory explains why a social program/intervention generates particular outcomes in particular contexts, in terms of one or more mechanisms - that is how the program's infrastructure and resources trigger particular decisions or behaviors in human participants. Program theories are usually 'middle-range' - that is, specific enough to generate propositions that can be tested about aspects of the program but sufficiently abstract to be applicable to other programs. Mechanisms are contingent: they are causal processes that have a tendency to occur in a particular set of conditions, but which do not always occur (because the circumstances have to be right for any particular mechanism to operate, and because many mechanisms can operate concurrently, sometimes cancelling each other out).

The validity of a review which is described as 'realist' and which talks about program theories or mechanisms but which expresses these as simple and linear relationships between variables should be questioned.

The findings of a realist synthesis consist largely of inferences about the links between context, mechanism and outcome and the theory(ies) that seek to account for these links. It is important that where inferences are made these are clearly articulated. Where possible, especially for key findings, it is important to include an explanation to show how these inferences were arrived at.

Transparency of the synthesis process can be demonstrated, for example, by including such things as a detailed worked example, verbatim quotes from primary sources, and (if appropriate) an exploration of disconfirming data (that is, findings which appeared to refute the program theory but which, on closer analysis, could be explained by other contextual influences).

When presenting inferences about context-mechanism-outcome configurations, reviewers should be clear about what they have categorized as context, what as mechanism and what as outcome. In a realist synthesis a mechanism involves the interaction between particular inputs (or resources) and human reasoning, which produces a particular outcome (or not).

More than one piece of data might be needed to support an inference. It is sometimes appropriate to build the argument for an inference as an unfolding narrative in which successive data sources increase the strength of the inference [32]. Provide enough details about each data item to identify its source and enable readers to make judgements about its relevance and rigor.

**Discussion section**

The following Items should be reported in the discussion section.

***Item 15: Summary of findings***

Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s).

**Example**

"This realist review of 249 primary studies has produced two key findings which are important, if somewhat unsurprising. First, Internet-based courses must engage their target group of learners to use the technology. This is likely to occur only if the technology is perceived as 'useful' (e.g.increases access to learning or saves time) and 'easy to use', though benefits in the former can outweigh challenges in the latter. Second, 'interactivity' is highly valued by learners. Learners wanted to be able to enter into a dialogue with the course tutor, fellow students and/or a virtual tutorial and obtain ongoing feedback on their understanding and performance." [29]

**Explanation**

In order to place the findings in the context of the wider literature and any specific policy need, it is necessary to summarize briefly what has been found. This section should be succinct and balanced, explaining the relevance of one or more key theories that emerged from the analysis and highlighting the strength of evidence for the main inferences. This should be done with careful attention to the needs of the main users of the synthesis.

***Item 16: Strengths, limitations and future research directions***

Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged.

The limitations identified may point to areas where further work is needed.

**Example**

"We explicitly chose to do a realist review of the RCTs [randomized controlled trials] to see what they could additionally yield. While the CHWs [community health workers] were an important component of the interventions being tested in the RCTs, none of the RCTs under review explicitly focused on performance of the CHW as an outcome. The RCTs under review offered a fair amount of information about the interventions, only some information about context - allowing us to formulate only generic hypotheses. ...

... Authors seldom described or discussed the mechanisms that explained their study outcomes. We realise that

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the RCT design, the exacting reporting requirements and word limits of journals, restrict authors from sharing all their operational experiences. In addition RCTs tend to report average effects and not differential effects of interventions, and less so of the context and rarely of the mechanisms triggered by their interactions. This makes the RCTs less useful for answering the questions regarding how interventions work. These generic hypotheses seem to be recurring in the literature, however they have not been explicitly tested across contexts." [27]

**Explanation**

Realist synthesis may be constrained by time and resources, by the skill mix and collective experience of the research team, by the scope of the review's questions or objectives and/or by anticipated or unanticipated challenges in the data. These should be made explicit so that readers can interpret the findings in the light of them. A common challenge in realist synthesis is that in order to focus the synthesis, some material is omitted at each successive stage. Some aspects of the topic area, therefore, end up being reviewed in detail and rich explanatory insights produced for these. Other aspects are neglected (relatively or absolutely). It is thus inevitable that in generating illumination, the synthesis will also cast shadows. These should be highlighted in the discussion so as to indicate areas where other syntheses might focus.

Strengths and/or limitations associated with any modifications made to the synthesis process should also be reported and justified.

***Item 17: Comparison with existing literature***

Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic.

**Example**

"We were unable to find any comparable attempt at providing an evidence-based-policy framework such as ours. However, we acknowledge that some sections of our framework may be found in sources we have not uncovered and also as tacit knowledge within the heads of seasoned practitioners (e.g. advocates or legislators). We do however hope that our attempts to develop and test it on our one 'case study' will make a primordial tool that will be useful to policy and decisions makers less well versed in the arena of public health legislation." [26]

**Explanation**

Comparing and contrasting the findings from a synthesis with the existing literature may help readers to put these into context. For example, this item might cover questions such as: How does this synthesis compare to other reviews (for example, were they theory-driven?); What does this synthesis add?; Which body of work in particular does it add to?; Has this synthesis reached the same or different conclusion to previous reviews?; and Has it answered a question previously identified as important in the field?

***Item 18: Conclusion and recommendations***

List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.

**Example**

"Our realist review was based on a housing intervention in the United States, but the results can potentially be applied to urban centers in other nations that implement housing interventions that involve moving families. When a family moves, the experience is likely to be different for each member of the household, and differences in mental health outcomes of moving may occur (Reference x1). All communities, rich or poor, and irrespective of geographic location, should be viewed as complex systems, and as composed of people with social relationships that influence the functioning and health of community members." [28]

**Explanation**

A clear line of reasoning is needed to link the findings (Results section) with the implications (Discussion and/or Conclusion). If the synthesis is small and preliminary, or if the coherence and plausibility of evidence behind the inferences is weak or moderate, statements about implications for practice and policy should be appropriately guarded.

If recommendations are given, these should take into account the focus of the synthesis and needs of the intended audience and be presented appropriately. The explanations in realist analysis are highly dependent on contextual influences. It follows that recommendations must be contingent (for example, only under certain contexts will a particular mechanism be triggered to generate the desired outcome) rather than statements that X should or should not be done.

***Item 19: Funding***

Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers.

**Example**

"We gratefully acknowledge a financial contribution from the Dutch Development Cooperation (DGIS)." [25]

**Explanation**

The source of funding for a synthesis and/or personal conflicts of interests may influence the research question, methods, data analysis and conclusions. No review is a 'view from nowhere', and readers will be better able to interpret the review if they know why it was done and for which sponsor.

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If a synthesis is published, the process for reporting funding and conflicts of interest as set out by the publication concerned should be followed.

## Discussion

We have developed these publication standards for realist synthesis (which we view as synonymous with realist review) by drawing together a range of sources - namely, existing published evidence, a Delphi panel and comment, discussion and feedback from a mailing list, training sessions and workshops. We hope these standards will lead to greater consistency and rigor of reporting and, thereby, make the outputs of realist synthesis more accessible, usable and helpful to different stakeholders.

This publication standard is not a detailed guide of how to undertake a realist synthesis. Other resources, both published (see Background) and in preparation, are better suited for this purpose. These standards have been developed as a guide to assist the quality of reporting of realist syntheses and the work of publishers, editors and reviewers. As part of the RAMESES project, we will be developing and disseminating both training materials and quality standards for realist synthesis [20].

Because realist synthesis is used for a broad range of topics and questions, and because it involves making judgements and inferences rather then checking against or following a technical checklist, it is impossible to be prescriptive about what exactly must be done in a review. The guiding principle is that transparency is important, as this will help readers to decide for themselves if the arguments for the judgements made were reasonable, both for the chosen topic and from a methodological perspective. We strongly encourage review authors to provide detail on what they have done and how - in particular with respect to the analytic processes used. These standards are intended to supplement rather than replace the exercise of judgement by editors, reviewers, readers and users of realist syntheses. We have tried to indicate in each item where judgement needs to be exercised.

The explanatory and theory-driven focus of realist syntheses means that detailed data may need to be reported in order to provide enough support for inferences and/or judgments made. While developing these publication standards, it became apparent that in some cases the word count limitations imposed by journals did not enable review teams to fully explain aspects of their synthesis - such as how judgments were made or inferences arrived at. Alternative ways of providing the necessary detail may need to be found, such as online appendices or additional files available from authors on request.

Previous efforts to develop publication standards have sometimes been criticized for being too 'ivory-tower' and failing to take account of real-world problems faced by reviewers. In an effort to redress this problem in the RAMESES project, we sought from the outset to engage not just senior academics but also junior and mid-career researchers, practitioners, policymakers and publishers in the development of the standards and to capture real-life challenges of ongoing realist syntheses as these emerged.

## Conclusions

We have developed these publication standards for realist syntheses by drawing on a range of sources. Our hope is that these standards will lead to greater consistency and rigor of reporting and make the outputs of realist syntheses more accessible, usable and helpful to different stakeholders. Realist synthesis is a relatively new approach to evidence synthesis and with increasing use and methodological development, changes are likely to be needed to any publication standards. We hope to continue capturing and improving these publication standards, through our email list [21] and wider links and discussions with researchers and those who commission, sponsor, publish and use realist syntheses.

### Abbreviations

ESRC: Economic and Social Research Council; RAMESES: Realist And MEta-narrative Evidence Syntheses: Evolving Standards).

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**Authors' contributions**

GWo carried out the literature review. JB searched the literature for realist syntheses. GWo, TG, GWe and RP analyzed the findings from the review and produced the materials for the Delphi panel. They also analyzed the results of the Delphi panel. GWo, TG, GWe and RP conceived of the study and participated in its design. GWo coordinated the study and ran the Delphi panel. All authors read and approved the final manuscript.

**Competing interests**

The authors declare that they have no competing interests. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR program, NIHR, NHS or the Department of Health.

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**References**

1. Pawson R: *Evidence-based Policy: A Realist Perspective* London: Sage; 2006.
2. Pearson M, Coomber R: **The challenge of external validity in policy-relevant systematic reviews: a case study from the field of substance misuse.** *Addiction* 2010, **105**:136-145.
3. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A: **Synthesising qualitative and quantitative evidence: a review of possible methods.** *J Health Serv Res Policy* 2005, **10**:45-53.
4. Barnett-Page E, Thomas J: **Methods for the synthesis of qualitative research: a critical review.** *BMC Med Res Methodol* 2009, **9**:59.
5. Pope P, Mays N, Popay J: *Synthesizing Qualitative and Quantitative Health Research: A Guide to Methods* Maidenhead, UK: Open University Press; 2007.
6. Gough D, Oliver S, Thomas J: *An Introduction to Systematic Reviews* London: Sage; 2012.
7. Kastner M, Tricco A, Soobiah C, Lillie E, Perrier L, Horsley T, Welch V, Cogo E, Antony J, Straus S: **What is the most appropriate knowledge synthesis method to conduct a review? Protocol for a scoping review.** *BMC Med Res Methodol* 2012, **12**:114.
8. Merton R: *On Theoretical Sociology. Five Essays, Old and New* New York: The Free Press; 1967.
9. Astbury B, Leeuw FL: **Unpacking black boxes: mechanisms and theory building in evaluation.** *Am J Eval* 2010, **31**:363-381.
10. Shepperd S, Lewin L, Straus S, Clarke M, Eccles M, Fitzpatrick R, Wong G, Sheikh A: **Can we systematically review studies that evaluate complex interventions?** *PLoS Med* 2009, **6**:e1000086.
11. Rycroft-Malone J, McCormack B, Hutchinson AM, DeCorby K, Bucknall TK, Kent B, Schultz A, Snelgrove-Clarke E, Stetler CB, Titler M, Wallin L, Wilson V: **Realist synthesis: illustrating the method for implementation research.** *Implement Sci* 2012, **7**:33.
12. Robert E, Ridde V, Marchal B, Fournier P: **Protocol: a realist review of user fee exemption policies for health services in Africa.** *BMJ Open* 2012, **2**: e000706.
13. Pawson R: **Evidence-based policy: the promise of 'realist synthesis'.** *Evaluation* 2002, **8**:340-358.
14. Pawson R, Greenhalgh T, Harvey G, Walshe K: *Realist Synthesis - an Introduction. ESRC Working Paper Series* London: Economic and Social Research Council; 2004.
15. Pawson R, Greenhalgh T, Harvey G, Walshe K: **Realist review–a new method of systematic review designed for complex policy interventions.** *J Health Serv Res Policy* 2005, **10(Suppl 1)**:21-34.
16. Moher D, Hopewell S, Schulz K, Montori V, Gotzsche P, Devereaux P, Elbourne D, Egger M, Altman D, for the CONSORT Group: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trial.** *BMJ* 2010, **340**:c869.
17. Brouwers M, Kho M, Browman G, Burgers J, Cluzeau F, Feder G, Fervers B, Graham I, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L, AGREE Next Steps Consortium: **AGREE II: advancing guideline development, reporting and evaluation in healthcare.** *Can Med Assoc J* 2010, **182**:E839-842.
18. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D: **The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration.** *BMJ* 2009, **339**: b2700.
19. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S, SQUIRE Development Group: **Publication guidelines for improvement studies in health care: evolution of the SQUIRE project.** *Ann Intern Med* 2008, **149**:670-676.
20. Greenhalgh T, Wong G, Westhorp G, Pawson R: **Protocol - realist and meta-narrative evidence synthesis: evolving standards (RAMESES).** *BMC Med Res Methodol* 2011, **11**:115.
21. RAMESES JISCM@il: [www.jiscmail.ac.uk/RAMESES].
22. Wong G, Greenhalgh T, Westhorp G, Pawson R: **Realist methods in medical education research: what are they and what can they contribute?** *Med Educ* 2012, **46**:89-96.
23. Wong G: **The internet in medical education: a worked example of a realist review.** In *Synthesising Qualitative Research: Choosing the Right Approach.* Edited by: Hannes K, Lockwood C. Chicester, UK: Wiley-Blackwell; 2011:.
24. EQUATOR Network: [http://www.equator-network.org/home/].
25. Dieleman M, Gerretsen B, van der Wilt GJ: **Human resource management interventions to improve health workers' performance in low and middle income countries: a realist review.** *Health Res Policy Syst* 2009, **7**:7.
26. Wong G, Pawson R, Owen L: **Policy guidance on threats to legislative interventions in public health: a realist synthesis.** *BMC Public Health* 2011, **11**:222.
27. Kane SS, Gerretsen B, Scherpbier R, Dal Poz M, Dieleman M: **A realist synthesis of randomised control trials involving use of community health workers for delivering child health interventions in low and middle income countries.** *BMC Health Serv Res* 2010, **10**:286.
28. Jackson L, Langille L, Lyons R, Hughes J, Martin D, Winstanley V: **Does moving from a high-poverty to lower-poverty neighborhood improve mental health? A realist review of 'Moving to Opportunity'.** *Health Place* 2009, **15**:961-970.
29. Wong G, Greenhalgh T, Pawson R: **Internet-based medical education: a realist review of what works, for whom and in what circumstances.** *BMC Med Educ* 2010, **10**:12.
30. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, Sirett E, Wong G, Cargo M, Herbert CP, Seifer SD, Green LW, Greenhalgh T: **Uncovering the benefits of participatory research: implications of a realist review for health research and practice.** *Milbank Q* 2012, **90**:311-346.
31. Dieleman M, Kane S, Zwanikken P, Gerretsen B: *Realist Review and Synthesis of Retention Studies for Health Workers in Rural and Remote Areas* Geneva, Switzerland: World Health Organization; 2011.
32. Pawson R, Wong G, Owen L: **Known knowns, known unknowns, unknown unknowns: the predicament of evidence-based policy.** *Am J Eval* 2011.

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**Supplementary file 2: RAMESES publication standards checklist**

| | | |
|---|---|---|
| 1 | Title identified as realist review | Yes |
| 2 | Abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice. | Yes |
| 3 | Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area. | yes |
| 4 | State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review. | yes |
| 5 | Any changes made to the review that was initially planned should be briefly described and justified. | Yes |
| 6 | Explain why realist synthesis was considered the most appropriate method to use. | Yes |
| 7 | Describe and justify the initial process of exploratory scoping of the literature. | Yes |
| 8 | state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected. | Yes |
| 9 | Explain how judgements were made about including and excluding data from documents, and justify these. | Yes |
| 10 | Describe and explain which data or information were extracted from the included documents and justify this selection. | Yes |
| 11 | Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process. | Yes |

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| 12 | Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). | Yes |
| 13 | Provide information on the characteristics of the documents included in the synthesis. | Yes |
| 14 | Present the key findings with a specific focus on theory building and testing. | Yes, although theory testing was limited due to limited evidence, this is discussed in the paper |
| 15 | Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s). | Yes |
| 16 | Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged. The limitations identified may point to areas where further work is needed. | Yes |
| 17 | Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic. | Yes |
| 18 | List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice. | Yes |
| 19 | Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers. | Yes |

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Supplementary file 3: Data extraction form

# Theory Areas

1. **If a change agent supports staff to understand how to interpret and respond to PLWD behaviour that uses PCC approaches, challenges poor practice by using experiential learning and patient centred resources and reflection, then staff will be more likely (mechanism confidence, awareness, prioritise) to engage and assess patient pain / distress and involve PLWD and carer in planning their care**

2. **If a change agent has organisational and clinical authority to introduce learning and credible resources that prioritise the identification and care of PLWD and addresses concerns around risk and workplace disruption within a PCC framework then staff will feel they have permission to do the right thing becoming less risk averse**

3. **If a change agent works as a clinical expert to identify and resolve the care needs of PLWD then staff will feel supported and be more willing to care for PLWD**

| ***Source**(ref):* | |
|---|---|
| **Author lens** | |
| **Country** | |
| **Type of study/paper** | |
| **Intervention** | |
| **Relevance:**<br>*Are the contents of a section of text within an included document referring to data that might be relevant to our mid-range theories? Which ones?* | |
| | |
| 2. Outcomes of interest<br>Are the outcomes of interest referred to in the paper? Which ones? | |
| 1) Patient and carer involvement in decision making<br>2) Length of hospital admission<br>3) Occurrence of adverse incidents (falls, nutrition, delirium)<br>4) Use of antipsychotic medication<br>5) Needs assessment<br>6) Patient and carer satisfaction<br>7) Other not specified | |
| **What are the characteristics of the change agent** | |
| | |
| **What are the characteristics of person centred care** | |
| | |
| **What is the change agent trying to do** | |
| | |

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|---|
| **What resources are in place to help them achieve their aims** |
| |
| **To what extent are their aims achieved, what is the evidence?** |
| |
| **In what context is the change agent working?** |
| |
| **3. Interpretation of meaning:**<br>*If it is relevant, do the contents of a section of text provide data that may be interpreted as being context, mechanism (resource/response) or outcome?* |
| |
| **4. Judgements about Context-Mechanism-Outcome-Configurations:**<br>*What is the Mechanism (resource)-Context-Mechanism (response)-Outcome Configuration (CMOC) (partial or complete) for the data?* |

| Resource/Intervention | Context | Mechanism | Outcome |
|---|---|---|---|
| | | | |

| |
|---|
| **5. Judgements about mid-range theory:**<br>• *How does this (full or partial) CMOC relate to the mid-range theory?*<br>• *Within this same document are there data which informs how the CMOC relates to the mid-range theory?*<br>• *If not, are these data in other documents? Which ones?*<br>• *In light of this CMOC and any supporting data, does the mid-range theory need to be changed?* |
| |
| **6. Rigour:**<br>• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the CMOC?*<br>• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the mid-range theory?* |
| |
| **7. Population** |
| |
| **Questions raised not captured elsewhere** |
| |
| **Notes** |
| |

Supplementary file 2

Evidence for theory area 1: To support staff awareness and learning

| Paper | Example Evidence | Key Points and emerging CMOs |
|---|---|---|
| Baillie (2015) [59] | "I think the Barbara's Story made me more aware of them so I go to help them where perhaps I may not necessarily have noticed them before. (Therapists1)" (p26)<br><br>"After seeing the video it makes those kinds of patients easier to speak with and it also reassures you, so for example in the video it talks about not taking them out of their own reality, and I think that just reassures people that you can distract them and not 'lie' to them and that's okay, and I think that's reassuring to people that don't know that much about dementia." (p46)<br><br>"Staff remembered Barbara being 'lost', 'confused', 'vulnerable', 'scared' and 'worried'. They engaged with her as a person who could be a family member… Some staff specifically related Barbara's Story to a family member, which personalised the film's story… There was also acknowledgement that any of us could find ourselves in a similar situation." (p24)<br><br>"Barbara's Story enabled staff to see her healthcare experience from her perspective and the behaviour shown in the film prompted staff to reflect on their own behaviour and that of colleagues." (p23)<br><br>"In most focus groups, staff discussed how their own interactions with patients and behaviour had changed since watching Barbara's Story, and they often referred to changes they had observed in other staff too. Areas discussed included: giving more time to patients, improved communication, giving more information, and assisting patients who are looking lost." (p25) | Raising awareness to recognise signs and symptoms of dementia<br><br>Training to improve confidence in working with people living with dementia<br><br>Reassurance from examples in training of how to work well with people living with dementia<br><br>Training that developed empathy helped staff relate to people living with dementia as family members<br><br>Shown experience from patient's viewpoint to understand how need to adapt care practices<br><br>Changes staff implemented after training; time for patients, better communication, information, recognising and acting upon distress and confusion. |

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| | Some participants considered that Barbara's Story had raised the profile of initiatives and other work that was already in place for people with dementia, further reinforcing and helping developments to embed in the Trust, such as dementia study days and dementia champions and use of the forget-me-not." (p29) | Training supporting and promoting the use of other resources. |
| | "Staff related how they listened to patients with a history of dementia, taking their physical symptoms more seriously, rather than attributing them to their dementia: 'we will now investigate it a little bit more [...] any physical symptoms we will take seriously' [rather than attributing it to their dementia or mental health condition (Nurse10). Similarly, in relation to behaviour, another nurse said:<br>I think it's really important for staff to remember not to play a part in that stigma and not to make excuses if they're upset or aggressive, not to put it down to their condition, sometimes they are just genuinely wanting something or upset. (Nurses8)" (p51) | Staff reported changes to practices following training. Understanding behaviours as communication of other needs rather than symptoms of dementia. |
| | "Those who had used This is me were great advocates for the tool and the difference it made in practice:<br>I saw it once in practice and I thought to myself, this is the best thing that anyone has ever done because it just made the care you gave so personalised and I remember the patient and it said in the notes, loves Coronation Street and EastEnders. So at 7.30pm I'd go and put on Coronation Street, just because I knew about it. (Nurses4)<br>… It's nice to know a bit more about them, what they like and don't like, even if it's just down to how they like their tea or they don't like tea. (Nurses6)" p53 | Use of biographical tool to understand the preferences and routines of the patient. |
| | In one focus group, an example of the benefits of This is me was explained:<br>She [patient with dementia] was in for less than three days, got home, she wasn't a delayed discharge but my point had been if This Is me hadn't been filled in and she was distressed and constantly calling, they'd have given her [medication], shut her up, then she'd have been over-sedated, she wouldn't have been eating and drinking, her delirium would have been worse. (Nurses4) | How not knowing about the patient leads to distressed behaviours that might have adverse results such as inappropriate medication, poor nutrition and hydration, and increased severity of delirium. |

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| Banks (2014) [40] | "[this is me] By having this document we have reduced the amount of medication the patient receives in hospital. Staff are much more likely to look into why the patient is behaving this way rather than get them prescribed medication. This in turn has reduced the number of falls during the day, therefore reducing the number of fractures and increased stays in hospital. P727<br><br>The first change we made was to stop separating the patient with dementia from the relative during the admission process. ... I think the relatives feel more valued as a carer and the importance of their role in looking after their relative with dementia is recognised. The patients are also much more relaxed to have familiar faces around so the admission process has become much smoother for everyone including the staff p727<br><br>I have tried to take back to the ward with me topics that I have learned and shared with other members of staff. This has been an eye opener as some staff are not keen to accept change and question everything that I have tried to do and don't seem to see the need for change. P728 | Resources that support knowledge of the patient reduce adverse events such as inappropriate medication, falls, and increased length of stay. Resources that support knowledge of the patient encourage staff to understand behaviour as a form of communication.<br><br>Changing processes and procedures that understand the needs of people living with dementia to reduce patient distress and improve carer satisfaction.<br><br>Difficulty in getting staff to change practices if they do not recognise the need to change practices. |
| Brooker (2014) [63] | "[Dementia awareness training] It has made a big difference to how staff respond to the behaviour of patients with dementia, as it has increased understanding and awareness. For example, there is now a greater focus on occupying patients with activities to reduce behaviour that challenges, and staff are now seen to be walking around with patients with dementia who are wandering when previously they would have told them to sit back down." P48 | Dementia awareness training improves staff understanding of how to better support people living with dementia. Understand the need for providing activities to reduce onset of behaviours that challenge and adapting way of working. |
| Dowding (2016) [60] | Participants discussed how pain may be intermittent and fluctuate, often only being present when patients are engaged in certain activities. ''often the doctors will go round and they'll ask the patient in their bed or in their chair, ''Oh, are you alright? Any pain anywhere?'', ''No, I'm fine''. As soon as we [physiotherapists] come, get them up on it, ''Oh, oh, that really hurts''.[H1, physiotherapist] p156 | Need to understand people living with dementia have difficulty communicating their needs (e.g. pain relief) and will have problems recalling and describing experiences of pain. |

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| | As with other patients, one of the challenges faced by clinicians is the initial recognition of whether or not a patient may be in pain at all; for a variety of reasons patients (including those with cognitive impairment) may not be able to verbally express they have pain, and clinicians often find it challenging to interpret behavioural signals which may be 'atypical' in nature. p157<br><br>One of the key factors in assessing and managing pain is the ability to build a 'picture' or narrative of the patient case; which is used as the basis for the interpretation of cues, to try and 'make sense' of a situation. Participants highlighted the importance of building patterns of information cues and patient behaviour, to help inform their decision making. This narrative occurred over time (an issue which arose in other themes from the data), trying to link different events over the trajectory of a patient stay, to help test 'guesses' and form the basis of trial and error approaches to management. P157<br><br>From the observations it appeared that pain recognition, assessment and management was carried out over time, by many individuals. Rather than being under the control of one specific nurse or other health care professional, it could be characterized more as a process of distributed work, which is time dependent. This is reflected in the comments in interviews, which highlight how there is a division of labour in the hospital ward; there numerous people with different professional roles who are all involved in the care of each patient, each with specific duties, responsibilities and powers. In turn, these roles often governed which part of the pain recognition, assessment and management process they participated in, and how they communicated their findings. p158 | Challenges for staff to understand patient needs.<br><br>Getting to know the needs of the patient through time and continuity in their care.<br><br>Context of ward where responsibilities for the patient's needs are across a number of staff; those who recognise the need may not be able to directly address the need. Importance of communication with colleagues. |
| Duffin (2013) [64] | 'Some people have been moved to tears by the DVDs,'(outcome) says Ms Karasu. 'The films resonate with them. Sometimes you see a look on their face and you can tell they are thinking: "I never thought of that." (reasoning) P16 | Emotional engagement with training and realisation of the patient's experiences of care. |

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| | In one training session nurses, doctors and other staff wear specially designed goggles that restrict their vision, and put on a jacket which has small splints inserted in the arms to restrict movement of their upper body. This is to help staff understand the physical constraints faced by some older people. Darlene Romero, a matron across the trust's three older people's wards, who delivers the training, says: 'It's a real eye opener, and makes you realise how difficult it can be to go to the toilet. P16<br><br>A laminated symbol of a forget-me-not is placed above the beds of all patients with dementia, and a similar motif is put on their casenotes, so that any health worker who comes into contact with them is aware of their condition. Ms Wood says: 'It shows our team that they need to adapt because the person with them has a cognitive impairment. If someone goes to have an X-ray, for example, the team would see the forget-me-not symbol and they would know that this person may not just jump up onto the couch and be ready. They will need to provide more explanation and perhaps to stay a bit calmer than they would with other patients to show extra sensitivity. P17 | Experiential learning triggering realisation of patient needs.<br><br>Identifying a patient has dementia, staff recognising they need to adapt care to be appropriate to the needs of the patient. |
| Edvardsson (2012) [65] | The subtle initial expression of emerging needs were not picked up by staff as they were absent and the expression of unmet needs could escalate to become behavioural alterations as the need remained unsatisfied. When staff finally came about, they were observed to interpret the behaviour as 'disruptive' or 'disturbing' as they lacked the initial interpretative cues that could explain the behaviour. As a consequence, care became very much reactive, as staff had to come up with acute solutions to full-blown situations for which they lacked the insight and an interpretative framework. P6 | Care becomes reactive when behaviour is misinterpreted. Underlying causes not investigated. |
| Ellison (2014) [42] | Colleagues reported improved skills, knowledge and understanding as well as improved confidence in caring for people with dementia as a result of the training and working alongside a Champion. Colleagues also reported changes in their practice as a result of training, for example:<br>spending more time with people with dementia on a one to one basis to provide more | Training supported by a Champion to improve knowledge and understanding of dementia and confidence to work well with people living with dementia. Staff reported changes to care practices. |

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| | individualised care; more effective communication as a result of a better understanding of the needs of people with dementia; involving carers more proactively; understanding the importance of personal care plans and documentation; being more aware of the impact of the environment on people with dementia; being more proactive in providing additional assistance to people with dementia; being prepared to challenge bed moves involving people with dementia when there was no clinical need; increased awareness of signs of stress and distress and seeking to identify the cause rather than resort to use of sedatives. p51 | Staff seeking to address underlying need of people living with dementia rather than treating behaviour with medication. |
| | The primary actions undertaken in this respect have been the implementation of person-centred care planning through use of the 'This is Me' document initially, and subsequent development and implementation of 'Getting to Know Me'. Many DCs have played a key role in implementing and trying to embed these documents through introducing it to their team and training staff in its application. … Use of GTKM allows staff to find out more about the patient and their preferences and is generally considered a useful tool in supporting improved person-centred care for people with dementia. Comments from Champions and their colleagues working in acute settings suggest that use of person-centred plans like this represents a departure from the norm for them in terms of the information they are used to collecting and the conversations they are used to having with patients. Examples were cited where staff have used GTKM more effectively minimise stress and distress, reporting how the information they gained about the patient through the assessment had supported them to recognise and respond more effectively to distressed behaviour. p53 | Use of biographical tools to support person centred care practices that reduce distress.<br>Role of champions in supporting implementation of tool. |
| | In interviews DCs frequently cited the role they have played in influencing the behaviour of colleagues, for example by challenging inappropriate use of language when speaking to or speaking about people with dementia. p54 | Champions role in addressing negative staff attitudes towards people living with dementia. |

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| | "Staff's attitudes have changed hugely in A&E [as a result of DC's awareness raising of how noise and activity can cause distress] – you used to see someone with dementia and there would be 2 or 3 nurses with the one patient, each doing something else and the poor patient... now you see them going in one person at a time, calmer more quietly."p56 | Champion supports staff to understand difficulties faced by people living with dementia. Staff adapt practices to recognise and support difficulties. |
| Galvin (2010) [10] | [post training] The staff also recognized the need for improved communication skills with the patient, such as sitting and talking clearly, using nonverbal clues, and asking permission to touch the patient in order to improve care. | Training for staff to recognise the need to change practices.<br><br>Additional evidence of how training encouraged staff to implement new resources to improve care of people living with dementia (activity packs, volunteers, identification method for patients at risk of leaving the ward). |
| Goldberg (2014) [50] | Staff also appeared more accepting and understanding of mental health problems and patients on the Unit were more likely to raise concerns about their mental health and these would be responded to by staff. This could be because staff were more aware of mental health needs, because they had more conversations with staff in general (and thus the opportunity to raise such concerns) or it could be because they were cared for on a ward where all patients were cognitively impaired. (p1337)<br><br>The Unit provided a greater focus on the mental health needs of patients. Staff were more often observed assessing patients' cognitive abilities (using standardised tools and by questioning) than on standard care. P1337<br><br>Sometimes, skilled care on the Unit was not evident to observers, as patients who had the potential to exhibited distress behaviour were calm. In this observation Alex has been calmly walking up and down the ward for over an hour. A member of staff has always been walking with him and talking to him. Alex's aggression was only evident when something unexpected happened. P1337 | Awareness and understanding of dementia led staff to address patient psychological and mental health needs.<br><br>Use of assessment tools to understand patients' cognitive abilities.<br><br>Supporting patient choice and independence to reduce distress and the onset of behaviours that challenge. |

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| | Individual attention was given to patients at other times on the Unit with staff getting patients drinks or snacks outside of the meal and drink rounds and using touch when interacting with patients. P1338<br><br>However, the psychological needs of the patients on the Unit were high and a minority of patients would call out persistently for long periods of time. Staff would try to comfort or distract them… But the calling out would resume once the staff member left the patient and the conflicting demands on time meant staff would sometimes ignore their cries and attend to other patients, staff or documentation… Delivering care to patients with these behaviours could be exhausting and sometimes, particularly towards the end of a 'long day' (12 1/2 h shift), staff would ignore patients. P1338 | Staff working outside of ward routine to meet individual needs.<br><br>Constraints to addressing patient needs when unable to find out the cause, conflicting demands on staff time, and staff fatigue. |
| Gonski (2012) [66] | Staff members stated that they were sufficiently trained and a majority (n = 11) were able to confidently manage the behavioral problems. The respondents reported that they were able to build therapeutic relationships with both the patients and the carers and were also happy to provide help for both parties. In terms of communication, the nurses were very confident they could communicate with the patients, and therefore were able to interpret individual's needs. P62 | Training supports staff confidence to work with people living with dementia who have behaviours that challenge. Staff ability to communicate well with patients helps them build relationships with patients and understand their needs. |
| Luxford (2015) [67] | Early in the implementation period, a few clinicians reported difficulty in translating the carers' tips into a workable strategy for the hospital environment as they lacked confidence to write strategies based on 'non-clinical' tips. This issue was addressed through further training and the development of lanyards for clinicians to use which demonstrated how to write an effective TOP 5. P5<br><br>After implementing TOP 5, the majority of clinicians reported agreeing or strongly agreeing that TOP 5 was easy to use (91%), not time consuming (70%), decreased patient agitation and distress (74%), resulted in decrease use of restraint—physical or chemical (61%)—and made it easier to relate to carers (89%). P5 | Use of biographical tool supported by champions, training, and examples of how to implement information into care plan.<br><br>Use of biographical tool perceived to reduce patient agitation and distress and the use of restraints. |

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| Nichols (2002) [53] | "We built an interdisciplinary team that looks at the patient and the caregiver as a unit, works with them, and responds to the patient's behaviour as meaningful behaviour that needs to be understood. We understand that dementia patients have special needs. Using a team approach has allowed us to meet those needs in an acute care hospital." p186 | Working with carer to understand patient's needs. Understanding that behaviour is a communication of an unmet need. |
| Scerri (2015) [55] | Care worker (S32): I was thinking about this particular patient who did not need physiotherapy because he was here for respite care. He used to turn to all the staff to ask questions .. So every time I used to engage in a conversation with him and try to first calm him and reassure him because he was panicking and living in a situation as if it is real for him. P6 | Recognising patient needs and addressing them to reassure. Understanding from patient perspective. |
| Schneider (2010) [61] | We found that HCAs continuously ensured that patients were as comfortable as possible, some going out of their way to achieve this. One worker was even known to have sewed and adapted patients' clothing to maximise their comfort (and staff convenience, because this prevented frequent changes of clothing). Efforts were made to overcome language barriers between staff and non-English speaking patients and, when patients were distressed, HCAs often comforted them with actions as well as words: The male patient who becomes very distressed and cries was comforted greatly by H/CO who warmly cuddled up next to him, whilst on his observation, putting her arm around him and letting him snuggle into her, putting his head on her chest. (Fieldnote, Ward C) p28<br><br>We concentrate more, as you get to know the patients, the more you know their ways, you know their habits and if they've got a bad tummy and things like that and you get to know them; the job comes easier when you get to know them. It doesn't stop you getting hit sometimes, but you're aware of, you just get to know them and understand them a bit more. P47<br><br>"Invoking their practical autonomy, the HCAs also made minor adaptations within routines to suit individual patients. For example, medications were administered to all | Recognising and addressing patient needs to improve comfort for patients and benefit staff workload.<br><br>Importance of getting to know patients and benefits to workload.<br><br>Personalising tasks for needs of patients. |

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| | patients at approximately the same times every day on each ward, rather than being doled out individually; this ensured that every patient received his or her medication, as well as conserving staff time. However, within this routine, HCAs who were 'running' the medications would often make small concessions, for example by taking extra time to gain the trust of individual patients." P 49 | |
| Spencer (2013) [52] | Carers of patients with MMHU described staff as being 'well prepared' for dealing with confused patients, displaying patience and compassion. Respondents noted that patients who liked to wander were guided by staff when walking up and down rather than constantly being returned to their bed space, a behaviour observed by carers on standard care wards. P3<br><br>"Participants felt that staff had little understanding and limited training in dementia care, which carers felt resulted in patients being ignored, shouted at or threatened when staff were faced with uncooperative or challenging situations." P3 | Staff who have understanding of dementia and dementia care can meet the needs of patients.<br><br>Where staff lack understanding of behaviours that challenge they misinterpret them and attribute the problem to the patient, leading to poor care. |
| Waller (2015) [49] | Many of the environmental changes appear to have occurred as a consequence of the training that teams received before they started planning their projects. For example changes in staff attitudes such as investing in table cloths, laying tables, and purchasing coloured crockery, as well as increases in activities for patients such as the provision of newspapers or implementation of therapy hours, were reported; in the words of one team member, it is 'not just about the colour of the paint'. P64<br><br>Making spaces seem smaller and more familiar, and reducing the numbers of decisions that have to be made by patients in finding their way to places such as the toilet, the dining room or their own bed space, seems to significantly reduce agitation. P65 | Staff training helps staff recognise the needs of people living with dementia and make adaptions.<br><br>Changes that recognise the difficulties of people living with dementia will help reduce distress. |
| White (2016) [12] | Patients with any form of BPSD during their admission were five times more likely to have an antipsychotic prescribed during the admission (OR 4.99, 95% CI 1.15, 21.70, p=0.032). Antipsychotic prescription was five times more likely in people who | Behaviours that challenge increase likelihood of antipsychotic prescription. |

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| | experienced hallucinations (OR 5.04, 95% CI 2.10, 12.06, p≤0.001) or activity disturbances (OR 5.71, 95% CI 2.22, 14.70, p≤0.001) and seven times more likely with aggressive behaviours (OR 7.70, 95% CI 2.25, 26.31, p=0.001). Patients were three times more likely to have an antipsychotic prescribed when they experienced sleep disturbance (OR 3.35, 95% CI 1.45, 7.79, p=0.005).<br><br>In total, 55% of participants received non-pharmacological management during their admission. The most commonly used techniques were psychosocial interventions (36%) and staffing (17%) (Table 2). We found no evidence in the nursing or medical notes of ongoing monitoring or review of the effectiveness of these non-pharmacological interventions, or of a systematic way of using these techniques. | Lack of monitor of non-pharmacological management of behaviours that challenge so difficult to know effectiveness. |
| Williams (2011) [39] | We are testing a REACH education programme for domestic assistants and housekeepers… They had not considered the positive impact they could have in contributing to care and, without exception, were delighted to support the initiative. P15<br><br>REACH helps all staff to understand the cognitive difficulties experienced by people with dementia. It enables them to contribute in their role and promotes pride in the part they play in care. p15<br><br>Carers feel relieved that their loved one's condition is recognised and that hospital staff know how to respond to them, while the carers' sheet allows families to pass on crucial information and tips that will keep patients safe and improve their care'. P17 | Understanding the problem, knowing how can make a difference to patient experience and being able to take pride in work.<br><br>Working with carers to get to know the patient and know strategies that work well to improve patient safety. |

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Supplementary file 5: Characteristics of included papers

| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Baillie, 2015 [59] | UK | Published report | Evaluation of Barbara's Story | Qualitative | Written responses and focus groups | Patient satisfaction, patient safety |
| Baldwin, 2004 [48] | UK | Published paper | RCT of mental health liaison team | Quantitative | Validated tools | Depression, cognitive impairment, referrals |
| Banks, 2014 [40] | UK | Published paper | Evaluation of dementia champion training programme | Evaluation | Questionnaires of trainee knowledge and confidence in dementia, qualitative analysis of trainee reports | Impact of intervention on PLWD |
| Bray, 2015 [62] | UK | Published paper | The use of bay nursing and activity with PLWD in hospital | Description of the use of bay nursing and activities co-ordinators | Dementia care mapping, Patient experience questionnaires | Patient satisfaction |
| Brooker, 2014 [63] | UK | Published report | Evaluation of Royal College of Nursing development training programme | Evaluation report | Online survey, site evaluation (including locally determined methods such as dementia care mapping, | Patient satisfaction, carer engagement, reduced distress |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | incident reporting and patient satisfaction survey) | |
| Dowding, 2016 [60] | UK | Published paper | Development of pain management tool for PLWD in hospitals | Ethnographic study | Interviews, non-participant observation, medical notes review, documentary analysis | The identification and management of pain |
| Duffin, 2013 [64] | UK | Published paper | Description of interventions to improve care for PLWD in hospitals | Discussion paper | n/a | Patient satisfaction, patient safety |
| Edvardsson, 2012 [65] | Sweden | Published paper | Understanding the psychosocial climate of a ward | Qualitative | Observation | Patient satisfaction |
| Elliot, 2011 [45] | UK | Published paper | Description of role of Dementia Nurse Specialist | Discussion paper | n/a | Patient experience, patient safety, needs assessments, patient involvement in decision-making |
| Ellison, 2014 [42] | UK | Published report | Evaluation of Dementia Champions and | Evaluation | Interviews, staff survey | Patient experience, assessment of |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | Dementia Nurse Consultants | | | needs, reduced distress, reduced behaviours that challenge |
| Enns, 2014 [71] | Canada | Published paper | Quality improvement trial to reduce the use of physical restraints in hospital | Step wedged trial | Medical notes review | Use of restraints |
| Galvin, 2010 [10] | USA | Published paper | Evaluation of dementia awareness training programme | Pre-, post-, and delayed post test | Questionnaires of staff knowledge and confidence in dementia, interviews with trainees | Patient experience, |
| Goldberg, 2014 [50] | UK | Published paper | Patient experience and care on a Medical and Mental Health Unit compared with care on general wards | Qualitative findings from RCT | Non-participant observation (structured (dementia care mapping) and unstructured) | Patient experience, reduced distress, reduced behaviours that challenge, supporting patient choice (walking about the ward, food outside of mealtimes) |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Goldberg, 2013 [51] | UK | Published paper | Patient outcomes on a Medical and Mental Health Unit compared with general wards | Quantitative findings from RCT | Interviews, medical notes review, used of validated tools, non-participant observation (dementia care mapping) | Days spent at home, health status outcomes, behavioural and psychological symptoms, physical disability, cognitive impairment, carer strain, carer psychological wellbeing, carer satisfaction, patient mood and engagement |
| Gonski, 2012 [66] | Australia | Published paper | Outcomes of PLWD treated on a behavioural unit in a hospital | Retrospective review of medical records | Medical notes review, interviews with staff and carers | Carer satisfaction, Patient health care outcomes, behaviours that challenge, mediation, falls |
| Harwood, 2010 [72] | UK | Unpublished report | Development of Medical and Mental Health Unit | Discussion paper | n/a | Patient experience, patient orientation to |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | | time, supporting patient abilities, patient safety, supporting patient choice (walking about the ward), patient referrals, behaviours that challenge, medication review, carer satisfaction, carer involvement |
| Luxford, 2015 [67] | Australia | Published Paper | Clinician-carer communication tool | Survey | Survey with staff and carers | Acceptability and perceived benefits for patients |
| Moyles, 2011 [68] | Australia | Published paper | Best practice, the use of 'specials' | Qualitative Interviews | Interviews with staff | Patient experience |
| Nichols, 2002 [53] | USA | Published paper | The development of a specialist dementia care unit | Discussion paper | n/a | Improved communication with carers, improved patient experience |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Rosler, 2012 [69] | Germany | Published paper | Treatment of PLWD with hip fractures on specialist ward compared with general ward | Matched pair analysis | Validated scales | Functional status, use of antipsychotic medication, length of stay |
| Scerri, 2015 [55] | Malta | Published paper | Person centred care in hospital wards | Appreciative Inquiry / Qualitative interviews | Interviews | Family carer satisfaction, patient experience |
| Schneider, 2010 [61] | UK | Published report | The role of health care assistants in caring for people living with dementia | Ethnographic study | Participant observations, Interviews | Patient experience |
| Spencer, 2013 [52] | UK | Published paper | Family carer perceptions of care on Medical and Mental Health Unit compared with general wards | Qualitative findings | Interviews with family carers | Carer satisfaction, carer perception of care |
| Upton, 2012 [70] | UK | Published report | Multi-component bundle of evidence-based interventions | Qualitative and quantitative findings | Interviews, survey, medical records | Ward moves, infections, weight, catheter use, falls, mobility, place of discharge, use of antipsychotics, patient and carer satisfaction |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Waller, 2015 [15] | UK | Published paper | Dementia friendly environmental adaptions in healthcare settings | Summary of findings of evaluations | Pre and post audit and locally determined data collection (observations, incident forms and falls data, medication review, interviews) | Behaviour that challenges, falls, patient engagement in activity, reduced agitation and distress, reduced use of antipsychotics |
| White, 2016 [12] | UK | Published paper | Management of behavioural and psychological symptoms of dementia in hospitals | Longitudinal cohort study | BEHAVE-AD scale<br>Non-participant Observation<br>Medical notes review | Behaviours that challenge and the use of pharmacological and non-pharmacological interventions for behavioural management |
| Williams, 2011 [39] | UK | Published paper | Development of the Butterfly Scheme | Discussion paper | Staff self-report for use of the scheme | Patient experience, identification and interpretation of behaviours that indicate a need (managing pain and continence), |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | | reducing patient distress, patient safety, carer satisfaction |
| Zieschang, 2010 [54] | Germany | Published paper | Feasibility study of dementia care specialist unit | Feasibility study | Staff survey, validated tools | Patient function, patient mobility, behaviours that challenge, length of stay, falls, use of restraints, use of antipsychotics |

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Supplementary file 6: Sample evidence from papers supporting CMOCs

| CMOC | Supporting evidence | Additional considerations or caveat evidence |
|---|---|---|
| CMOC 1: Understanding behaviour as communication to improve staffs' ability to respond | Banks (2014) [40]<br>One participant reported that use of the This is Me document had reduced the levels of medication prescribed and in turn the number of falls:<br>By having this document we have reduced the amount of medication the patient receives in hospital. Staff are much more likely to look into why the patient is behaving this way rather than get them prescribed medication. This in turn has reduced the number of falls during the day, therefore reducing the number of fractures and increased stays in hospital. (p727)<br><br>Galvin (2010) [10]<br>Participants were asked to rate their level of confidence in dealing with the hospitalized patient with dementia before and after the program. Participants reported a significant improvement in their overall confidence (Table | Spencer (2013) [52]<br>Standard care respondents felt that some staff displayed a negative attitude towards confused patients. Participants felt that staff had little understanding and limited training in dementia care, which carers felt resulted in patients being ignored, shouted at or threatened when staff were faced with uncooperative or challenging situations. In some cases, this led to a confrontation between nurses and family carers who reacted to what they perceived as unacceptable staff attitudes towards patients. These carers further highlighted that they had not formally reported for fear of repercussions towards their relatives:<br>She [health care assistant] kept shouting at him, turn over, turn over I can't get to you. So eventually I opened the curtains and said that man's confused he can't understand you. She [health care assistant] knew I was sitting |

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| | 2) as well as in each individual variable: assessment and recognition of dementia, managing dementia care, differentiating dementia from delirium, communicating with the patient and family and discharge planning. (p5)<br><br>Williams (2011) [39]<br>The carer's sheet asks about people's life history which can help staff talk to patients in a meaningful way, or distract or calm those who might be agitated. One woman had been a dance teacher so when she became agitated the nurses could talk about this or look at old photographs with her which helped to distract her. Another woman sometimes hit and kicked staff, but her son was able to tell us that this meant she was in pain, so again, we could respond accordingly. (p17) | outside the curtain and it didn't deter her, she was really shouting. (Wife of 69-year-old, male, standard care patient.) (p3)<br><br>Goldberg (2014) [50]<br>However, the psychological needs of the patients on the Unit were high and a minority of patients would call out persistently for long periods of time. Staff would try to comfort or distract them…. But the calling out would resume once the staff member left the patient and the conflicting demands on time meant staff would sometimes ignore their cries and attend to other patients, staff or documentation…. Delivering care to patients with these behaviours could be exhausting and sometimes, particularly towards the end of a 'long day' (12 1/2 h shift), staff would ignore patients. (p1338) |

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| CMOC 2: The role of experiential learning and creating empathy to encourage reflection for responsibilities of care | Baillie (2015) [59]<br>Barbara's Story engaged staff emotionally and prompted empathetic responses. They related to her as an individual and her experience. Staff related to Barbara as someone who could be their family member and for some staff, Barbara's experience mirrored their own family experiences. Staff expressed increased awareness of dementia and how it could be recognised, both within the Trust and outside. … Staff discussed how their own interactions with patients and behaviour had changed since watching Barbara's Story, and they often referred to changes they had observed in other staff too. Changes included:<br>giving more time to patients, improved communication, giving more information, and assisting patients who are looking lost. Staff also discussed how Barbara's Story had highlighted their professional responsibilities. (p28) | Baillie (2015) [59]<br>Time was a key constraint identified, along with the perception that 'people with dementia require a lot of your time' (Nurses8)…. Staff discussed the importance of having sufficient and high quality time for people with dementia (Nurses7, Nurses8) and the acknowledgement that time spent is of value:<br>Recognising that if you're spending one to one time with a person with dementia, whether it's walking around talking about where the boat goes from, that is valid. That's not, not doing work. (Nurses2) (p56)<br><br>Staff discussed how they put the Trust values into action. The value 'Patients first' had a strong resonance and there were many examples of going 'the extra mile' to benefit patients. Staff also discussed a perceived culture change within the Trust so that they felt able to spend longer with a patient or to challenge others about their practice. There |

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| | Duffin (2013) [64]<br>In one training session nurses, doctors and other staff wear specially designed goggles that restrict their vision, and put on a jacket which has small splints inserted in the arms to restrict movement of their upper body . This is to help staff understand the physical constraints faced by some older people. Darlene Romero, a matron across the trust's three older people's wards, who delivers the training, says: 'It's a real eye opener, and makes you realise how difficult it can be to go to the toilet.' (p16)<br><br>Williams (2010) [39]<br>REACH helps all staff to understand the cognitive difficulties experienced by people with dementia. It enables them to contribute in their role and promotes pride in the part they play in care. (p15) | was reference to standard setting and a new 'norm' having been established in the Trust. (p34)<br><br>Scerri (2015) [55]<br>Although family members appreciated that care is provided in time and when required, hospital staff felt that positive experiences with dementia patients can be achieved if they went the 'extra mile'; when they adopted initiatives or carried out actions that were not part of the normal care routine or that fall within their job description. (p6) |

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| CMOC 3: Clinical experts who legitimise priorities for care | Baldwin (2004) [48]<br>Liaison support comprised encouragement of person-centred care, education about mental disorder, nutrition and safety issues, and sign-posting to relevant services. Interventions were tailored to the patient and lasted for a maximum of 6 weeks. (p473)<br><br>Elliot (2011) [45]<br>As many ward doctors and nurses do not have adequate knowledge to address the needs of older patients who present with behaviour that challenges, part of the input from the DNS has focused on addressing this requirement, and this activity has assisted in reducing length of stay by discouraging inappropriate sedation, which generally contributes to poor patient outcomes. (p649)<br><br>Baillie (2015) [59]<br>Staff recognised that Barbara's Story had been developed within the context of the Trust | Goldberg (2014) [50]<br>Lisa walks down the walkway. The staff say ''Morning Lisa'' ''Morning'' as they walk past. . . Lisa says that this is a strange hospital. The auxiliary says ''If you want to go down that way with [the mental health nurse], she's lovely''. Lisa says ''You're all lovely''. The mental health nurse then talks to Lisa for some time. MMHU55. (p1339)<br><br>Ellison (2014) [42]<br>While Champions with different levels of seniority generally feel able to influence colleagues to some extent, challenging inappropriate attitudes and behaviour, implementing and embedding change within their own or other ward settings, and with other professional groups tends to be easier the more senior their position… "It's easier to address change with nurses if you're their manager" [SCN Champion - interviewee] (p34) |

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| | values and they discussed how they applied the values in action. There was recognition that each individual was representing the Trust and a sense of pride which prompted certain behaviours. There was also discussion about a culture change having taken place following on from Barbara's Story. Dementia was now seen as 'everybody's business' with a Trust-wide awareness. Staff discussed that Barbara's Story established standards expected within the Trust for patients generally and the expectation of improvement. It was also considered that Barbara's Story had established the role that all staff were expected to play in improving patients' experience, particularly for those who are most vulnerable. Barbara's Story had also set out an expectation for staff to be proactive about challenging care. (p60) | Nichols (2002) [53]<br>This change affected staff's job descriptions, the nature of their work, and what was considered important and not important… we did ask every member of the team… to sit down and think through how their jobs would be different if, in fact, they were responding to the needs of both the caregiver and the patient." (p187) |
| CMOC 4: Staff with confidence to adapt working practices and routines to individualise care | Edvardsson (2012) [65]<br>Sharing place and moment was characterised by staff actions such as: involving patients in | Rosler (2012) [69]<br>The CGU has additional components compared to conventional geriatric treatment: hidden exit |

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| | meaningful ways in tasks that had to be done; socially dining with patients; small talking with them in the day room; jointly performing different non-medicalised activities; or in other ways going beyond routines to make the content of the day mean a little extra for patients. The baseline activities at the ward consisted mostly of routine based medical tasks and the category sharing place and moment was observed when staff initiated different forms of leisure activities involving the patients. (p4)<br><br>Bray (2015) [62]<br>Bay nursing is a really positive move. I enjoy being more person focused, knowing what I am doing as a result of getting to know my patients better. Showers and baths can be offered more frequently and patients can have the time to do things more independently – that is, patients assisted to walk to the toilet as opposed to | doors, increased light in hallways and patient rooms, night lights, a treatment room on the wad to decrease patient transferral, a living and eating room, and a loop track for wandering patients. The number of beds was decreased from 28 (non-CGU ward) to 23 on the CGU. (p400)<br><br>Bray (2015) [62]<br>Bay nursing identifies one nurse as responsible for monitoring each bay for an entire shift, generally from 7.15am to 7.45pm, alongside a healthcare assistant. These two staff members have a maximum of seven patients under their care at any time. To achieve this, the 27-bed ward had two beds removed, one from a male bay and one from a female bay. The extra space was put to good use by introducing a communal table into each bay. (p22) |

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| | given a commode because of time pressures.' (p24)<br><br>Schneider (2010) [61]<br>Invoking their practical autonomy, the HCAs also made minor adaptations within routines to suit individual patients. For example, medications were administered to all patients at approximately the same times every day on each ward, rather than being doled out individually; this ensured that every patient received his or her medication, as well as conserving staff time. However, within this routine, HCAs who were 'running' the medications would often make small concessions, for example by taking extra time to gain the trust of individual patients. [p50}<br><br>Rosler (2012) [69]<br>In the CGU described here, physiotherapists and nurses tried to activate patients more individually by catching the right moment | |

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| | rather than working according to strict time schedules. However we cannot pin down the effect of a multidimensional intervention to a single factor. (p401) | |
| CMOC 5: Staff with responsibility to focus on psychosocial needs | Harwood (2010) [72]<br>The Occupational Therapist introduced occupational profiling using the Pool Activity Level instrument which was consistent with a person-centred care approach. This aims to identify the level of function for a patient on admission, and the development of care plans for personal care and other activities. As a result staff could engage patients in activities at a level where they could be successful, helping patients avoid the distressing experience of repeated failure. A health care assistant took specific responsibility for developing a programme of activities matched to ability using the occupational profile levels. She made contact with activities co-ordinators in the Mental Health Trust and kept a log of what she | Harwood (2010) [72]<br>What didn't work:<br>Activities co-ordinator not on duty every day; activities otherwise dependent on ward staffing levels. (p23)<br><br>Goldberg (2014) [50]<br>The staffing resources needed to keep patients safe could result in less time being available for other patients on the ward…. At times, activities coordinators and mental health nurses were allocated to watch the cohort bay, preventing their engagement in the organised activities and mental health assessments they were employed to provide. (p1338)<br><br>Bray (2015) [62] |

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| | had done. This included games (bowling, giant noughts and crosses, dominoes, ludo), quizzes, drawing and crafts, music, reminiscence, and exploration of senses. (p21)<br><br>Edvardsson (2012) [65]<br>The staff member involved all of the five patients in the day room in the activity, by talking to them interchangeably – each in a personalised way, asking for advice, comments and suggestions. It was a moment when she created a homely atmosphere through seeing, communicating and involving all persons present in the room at the same time. All of the patients present in the room expressed appreciation, interest and joy. (Field note no. 19, Friday 14.15, Day room) (p4)<br><br>Zieschang (2010) [54]<br>Daytime activities are conducted especially during the afternoon when staffing by the | Unfortunately, the ward has faced challenges because some of its staff have been moved to support other areas of the hospital, making it impossible to implement bay nursing at times because of inadequate staffing levels. This has been disheartening for staff that are unable to fulfil their new role, which they know has been effective. (p24)<br><br>Moyles (2011) [68]<br>The allocation of the special is ideally determined by the needs of the patient, yet in reality the allocation is more often determined by other constraints such as nurse shortages and budget constraints. However, it was clear that whatever the background of the special they generally did not have sufficient skills in how to care for a person with dementia. A MD expressed this as:<br>So they tend to call for a special, who will be someone who is extra, called in. Not necessarily a group of people who have experience in |

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| | nurses is reduced and the sun-downing phenomenon might occur. (p144) | aged care…it tends to be the most junior nursing staff with the least amount of education. (MD, P11) (p424) |
| CMOC 6: Building staff confidence to provide person-centred risk management | Zieschang (2010) [54]<br>Concern arose about promoting ambulation in a unit where patients are allowed to walk unassisted and where rejection of physical restraints might increase the number of falls and fall-related injuries especially fractures… Even though these events may happen, it is our estimation that the benefits of unrestricted ambulation outweigh the risks. Fall prevention interventions, such as review of medication, restrictive use of sedatives, adequate footwear and lighting are applied. (p143)<br><br>Nichols (2002) [53]<br>They [staff] observe that on this floor when patients in beds 6 through 21 get agitated, they can order restraints. But if patients in beds 22 through 30 become agitated, they are | Zieschang (2010) [54]<br>We promoted mobility on the unit among older and often frail patients with limited insight concerning their fall risk, the number of falls, especially injurious falls, appears to be an in important criterion to assess whether this concept of letting them wander at liberty is acceptable. (p141)<br><br>Bray (2015) [62]<br>The main challenge encountered when bay nursing was introduced was staff not understanding or appreciating that the bay could not be left unattended. It was reinforced to staff that if they left the bay the link with patients was lost and there was no one available to monitor patient safety or provide |

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| | supposed to go see the patient and find out why he or she is upset. (p186)<br><br>Luxford (2015) [67]<br>Surveys about the implementation process identified that the simplicity of theTOP5 process and strategies was considered by clinicians as the 'key to success'. Successful uptake relied on acceptability to staff and an existing culture of engagement with carers. Early in the implementation period, a few clinicians reported difficulty in translating the carers' tips into a workable strategy for the hospital environment as they lacked confidence to write strategies based on 'non-clinical' tips. This issue was addressed through further training and the development of lanyards for clinicians to use which demonstrated how to write an effective TOP 5. (p5) | assistance as required. Staff had therefore to ensure that appropriate cover was in place if they needed to leave the bay for any reason. As two members of staff are allocated to each bay, this was thought not to be overly restrictive, although it can become more challenging during longer shifts. (p23)<br><br>Galvin (2010) [10]<br>Hospital A instituted a "Code Green" procedure that placed patients at risk for elopement in green gowns and trained staff on appropriate dementia-friendly responses and precautions. (p10) |

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# Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review



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Title Page

**Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review**

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**Abstract**

Objectives: To identify features of programmes and approaches to make healthcare delivery in secondary healthcare settings more dementia friendly, providing a context-relevant understanding of how interventions achieve outcomes for people living with dementia.

Design: A realist review conducted in three phases (1) stakeholder interviews and scoping of the literature to develop an initial programme theory for providing effective dementia care; (2) structured retrieval and extraction of evidence; (3) analysis and synthesis to build and refine the programme theory.

Data sources: PubMed, CINAHL, Cochrane Library, NHS Evidence, Scopus, grey literature.

Eligibility criteria: Studies reporting interventions and approaches to make hospital environments more dementia friendly. Studies not reporting patient outcomes or contributing to the programme theory were excluded.

Results: Phase 1 combined findings from 15 stakeholder interviews and 22 publications to develop candidate programme theories. Phases 2 and 3 identified and synthesised evidence from 28 publications. Prominent context-mechanism-outcome configurations were identified to explain what supported dementia-friendly healthcare in acute settings. Staff capacity to understand the behaviours of people living with dementia as communication of an unmet need, combined with a recognition and valuing of their role in their care prompted changes to care practices. Endorsement from senior management gave staff confidence and permission to adapt working practices to provide good dementia care. Key contextual factors were the availability of staff and an alignment of ward priorities to value person-centred care approaches. Preoccupation with risk generated responses that were likely to restrict patient choice and increase their distress.

Conclusions: This review suggests strategies such as dementia awareness training alone will not improve dementia care or outcomes for patients with dementia. Instead, how staff are supported to implement learning and resources by senior team members with dementia expertise is a key component for improving care practices and patient outcomes.

PROSPERO Trial Registration Number: CRD42015017562

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**Strengths and limitations of this study**

- Applying realist methods enabled a theory-driven explanation of how dementia-friendly healthcare can be supported in hospital settings
- The process of the review facilitated the development of a new programme theory, which can be used to inform future initiatives that support people with dementia in hospital environments
- The involvement of stakeholders from the outset ensured the plausibility and relevance of the findings for hospital environments
- The extent of evidence to support some elements of the programme theory was limited, especially where interventions lacked specificity about process and patient outcomes.

**Key words**

People living with dementia, hospitals, dementia, realist review, dementia friendly

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## INTRODUCTION

There is increasing recognition that hospital staff and services need to understand the complexity of caring for and treating people living with dementia [1]. At any one time, 25% of hospital beds are used by people living with dementia, rising to a higher proportion on some wards [2]. Co-morbidities are common and many people are admitted to hospital for reasons not directly related to their dementia [3-5]. Healthcare outcomes for people living with dementia are variable across the country and are inequitable when compared to outcomes for people without cognitive impairments [5]. Adverse incidents occurring during admissions, such as falls, poor nutrition and hydration, infections, and the onset of delirium, contribute to longer stays and reduced functional abilities which may result in admission to a care home [6-8].

A number of factors may impact on the disparity of health outcomes for people living with dementia including: a lack of focus and leadership for dementia in hospitals [5]; healthcare staff who have inadequate knowledge and training in dementia and dementia care [9, 10]; difficulties faced by healthcare professionals when assessing the risk and benefits of treatment options [11]; widespread use of care practices which are detrimental to people living with dementia, such as the use of antipsychotics for behavioural management [12]; stigma and discrimination towards people living with dementia [13, 14]; and confusing, unsafe environments [15]. The National Dementia Strategy [16] aimed to improve the quality of care for people living with dementia in general hospitals through leadership that addresses quality improvements in dementia care, defined care pathways, and the use of liaison mental health teams. It also highlighted the importance of education and training to break down the stigma associated with dementia and to develop dementia awareness within the healthcare workforce. To address these ambitions, interventions have been designed and implemented with the aim of creating dementia-friendly healthcare in hospitals [17, 18].

### Dementia Friendly

The concept of dementia friendly developed from initiatives to promote age-friendly communities [19]. It was first used to describe physical and social environments that promoted inclusion, acceptance and accessibility for people living with dementia [20, 21] and includes initiatives supporting the independence and safety of people living with dementia [22]. In the UK, this includes the Dementia Friends initiative [23] and the Dementia Engagement and Empowerment Project (DEEP) [24].

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At the patient level, dementia-friendly healthcare is the practice and organisation of care that is aware of the impact dementia has on a person's ability to engage with services and manage their health. It promotes the inclusion of people living with dementia and their carer in treatments, care decisions and discussions, with the aim of improving outcomes for the patient and carer [16, 17, 25-27].

Interventions to promote dementia-friendly healthcare environments have been diverse in terms of their design and application in practice [27-29]. This review of the evidence acknowledges that the effectiveness of programmes to address the known problems of being a patient with dementia is contingent on multiple factors such as staff knowledge and skills in dementia care, the care environment, and the competing demands on staff time and attention. The review objectives were:

1. To identify how dementia-friendly interventions in hospital settings are thought to achieve the desired patient and carer outcomes
2. To develop evidence-based explanations to understand what it is about dementia-friendly interventions in hospitals that works for people living with dementia and their carers, in what circumstances and why.

**Realist Methodology**

Realist review is a theory-led method that applies the principles of realism to evidence review [30, 31]. In realism, change is not directly achieved by an intervention, rather change is generated through the influence of intervention resources and contextual factors on human reasoning. A realist approach seeks to explain how the relationship between these elements (context and mechanism) leads to particular outcomes (box 1) [30].

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Box 1: Glossary of realist terms

Context: refers to factors, including but, not limited to, personal, social, organisational, or policy aspects that influence the way resources are engaged with to generate outcomes. For example, staffs' professional focus may influence how they use information about a person's social, rather than medical, history, or an organisation's expectations for dementia care may affect how staff prioritise their work with patients with dementia.

Mechanism: includes the resource the intervention provides (such as training, assessments of pain, or access to biographical information about the patient) and the reasoning of the subjects, in this case the reasoning of staff (such as recognising the benefit of working differently) [32].

Outcome: the intended (or unintended) result. Patient outcomes of interest included; patient wellbeing, medication use (specifically analgesic and anti-psychotic), access to assessments, evidence of inclusion in care decisions, reduced distress, adverse incidents (such as falls or hospital acquired infection), length of stay, reduction in the onset of behaviours that challenge, maintenance of functions (such as activities of daily living).

Demi-regularity: a semi-predictable pattern of outcomes. For example, the provision of meaningful activities for patients with dementia will reduce their boredom and distress in hospital, leading to a reduction in the onset of behaviours that are challenging for staff.

Context-mechanism-outcome configuration: specifies the relationship between the features (context, mechanism and outcome). It is the unit of analysis which supports synthesis across studies to build and refine the programme theory.

Realist review was appropriate for this study as the evidence base for dementia-friendly interventions is in its early stages. As such, theory building derives from a variety of sources and study types. Complexity is inherent in both design and implementation of the interventions: they are multicomponent and rely on human agency that is influenced by individual, service and organisational pressures. Realist inquiry acknowledges these features and incorporates them to develop an explanatory account of how different aspects influence reasoning and outcomes [33].

## METHOD

Realist review methods were used to develop a theoretical understanding of what supports effective dementia care in hospital settings. There were three overlapping, iterative phases: 1) defining the scope of the review informed from key literature and stakeholder interviews; 2) structured searches, screening, and data extraction; 3) analysis and synthesis leading to refinement of the programme theory. A fuller account of the review protocol is available in Handley, et al. [34].

The phases did not follow a linear format, but informed and refined understanding throughout the review leading to new interpretations and building of evidence. Sources were identified and revisited, new evidence was incorporated, and inclusion criteria reconsidered as new theoretical understanding developed. The RAMESES publication standards informed the preparation of this report and has been vetted against RAMESES criteria (supplementary file 1 and supplementary file 2) [31].

### Changes to the review process

One change was made to the review process subsequent to the published review protocol [34]. The expert steering group workshop was not held. However, emerging findings and the refined programme theory were shared with the with Alzheimer's Society research network monitors (RP, JW, PM) who were volunteer representatives with experience of caring for family members living with dementia. They commented on the resonance and relevance of the inferences that contributed to the developing theory throughout the review process. Review findings were presented and discussed at a seminar on dementia-friendly healthcare with 75 participants, 19 of whom worked in hospitals. The findings are being taken forward for testing in a realist evaluation.

### Phases of the Realist Review

*Phase one: Defining the scope of the review: concept mining and theory development*

Evidence from interviews with stakeholders and a scoping of the literature was used to: 1) identify the range of dementia-friendly interventions in healthcare settings both in the UK and internationally, 2) determine possible theoretical assumptions about how and why interventions were thought to work (or not), and 3) clarify what were understood to be the significant mechanisms for change. Stakeholders, defined as people with experience in designing, implementing, and using dementia-friendly interventions, were identified from knowledge within the team, internet searches, and dementia-specific conference abstracts. They were purposively sampled from a range of settings (academia, healthcare, commissioning, social work, the community) and backgrounds (nursing, education,

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physiotherapy, research, person living with dementia) [34]. Stakeholders were not further involved in the development of the emerging context-mechanism-outcome configurations (CMOCs) or building the programme theory. Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

Data from interviews and the literature were coded using framework analysis [35] with emerging themes and competing accounts discussed and debated amongst the authors (MH, FB, CG) and with Alzheimer's Society research network monitors (RP, JW, PM). Mapping this evidence demonstrated limited understanding at the point of staff interaction with patients and how this influenced patient outcomes. A decision was made to focus the review on how interventions led to patient outcomes. Data from the interviews and literature were scrutinised for demi-regularities (see Box 1, glossary of realist terms) and informed hypotheses set out in the form of 'If… then statements'. These statements were used to define the conditions thought to be necessary to achieve: 1) staff outcomes, such as taking action to investigate the cause of patient behaviours and applying best practice with people living with dementia; and 2) patient outcomes, such as reduced distress, reduction in adverse incidents, and improved wellbeing. Discussions amongst the authors based on these statements led to the development of a conceptual framework [30]. Three overlapping theoretical propositions were generated to explain what supports the implementation and uptake of interventions that promote dementia-friendly healthcare within a ward based environment.

*Phase two: Retrieval and review*

*Searching for relevant studies*

Informed by the theoretical propositions derived from the work in phase one, search terms were revised. The inclusion/exclusion criteria were refined to focus on studies which reported patient outcomes and provided information about the characteristics and role of change agents (staff who supported the implementation and uptake of interventions).

Searches were limited to 2000 – 2015 to reflect the impact of the work of Kitwood and Bredin [36] on dementia care practices that recognise the importance of person-centred care and the promotion of personhood. In addition to the electronic database searches (box 2), we undertook extensive lateral searching, including forward and backward citations, and contact with experts. Additional searches were performed as emerging themes around the management of pain and behaviours that challenge became apparent. These were

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purposive searches that applied the same inclusion criteria. Theory development continued until theoretical saturation was achieved [37, 38] (box 2).

Box 2: Phase two search terms and search strategy

Searches initially run September 2015, search alerts scanned to February 2016

Language restricted to English

Date restricted 2000 – 2015

Search terms:

(dementia AND (friendly OR appropriate OR awareness OR champion OR liaison OR ward OR environment OR education OR training OR nurse specialist OR lead* OR person centred care) AND (hospital OR acute care OR secondary care))

Additional search terms developed from work in phase one:

dementia AND (change agent OR champion OR knowledge transfer OR knowledge translation OR opinion leader)

Additional search terms reflecting emerging themes in phase two. Searches ran January 2016, search alerts scanned to February 2016

(dementia AND (pain) AND (hospital OR acute care OR secondary care))

(dementia AND (behaviour* OR BPSD) AND (hospital OR acute care OR secondary care))

Databases:

Cochrane Library (incl. CENTRAL, CDSR, DARE, HTA) (244), CINAHL (610), PubMed (4253), NHS Evidence (819) and Scopus (410)

*Study screening and data extraction*

Search results were downloaded into EndNote bibliographic software and duplicates deleted. One author (MH) screened titles and abstracts identified by the electronic search and applied the selection criteria to potentially relevant papers. Full texts of potentially relevant manuscripts were screened for relevance (whether the study has contributed to specific propositions relevant to the theory building) and rigour (whether they were of sufficient quality to provide credible evidence to help refine specific components of the

proposition) [30, 31]. Appraisal of the contributions and reliability of evidence from papers continued throughout the synthesis through discussion with the other authors.

Data were extracted by one author (MH) using a bespoke data extraction form organised to establish contributions and challenges to the theories, and strengths and weaknesses of the studies. Study characteristics such as design, setting, participants and sample size were also recorded [31]. The data extraction form was piloted by MH and shared with the team for comment [supplementary file 3]. To reduce the potential for bias during data extraction, a sample of the papers and their completed data extraction forms (6/28) were shared with FB and CG to appraise the extraction process and identified data. Information about the role and work of the change agent, the resources provided by the interventions, the contextual features of the settings (e.g. workforce, knowledge of dementia), explicit and implicit theories for how interventions were anticipated to work, and patient and carer outcomes were extracted. Coded data from all the papers and their contribution to theory development were shared with FB and CG. Challenges to interpretations were discussed to test credibility. Evidence from the studies were first mapped to capture the complete range of possibilities of how different approaches and resources triggered different responses from patients, family, and staff. After discussion amongst the authors, data were organised into tables to reflect the theoretical propositions they addressed (supplementary file 4) and to assist comparison of data across studies.

*Phase 3: Analysis and Synthesis*

Data synthesis was led by MH and emerging findings were discussed with the team (CG and FB), and the research network monitors (RP, JW, PM). Deliberations assisted the refinement of propositions, ensuring that emerging theories were plausible and clear. Discussions of papers included: the key characteristics of members of staff who support the implementation and uptake of interventions, resources, and new ways of working with people living with dementia (change agents); resources from interventions and how they were thought to influence staff reasoning; the impact of context; and possible undesired outcomes (such as stigmatising practises and broad application of strategies at the expense of individual needs). The focus was on understanding how patient outcomes were achieved through the actions of staff and what had supported staff to behave in particular ways. Recurring patterns in context and outcome (demi-regularities) detectible across studies were explained by explicit or implicit mechanisms. This led to the development of context-mechanism-outcome configurations designed to explain what it is about an intervention that

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works, for whom, and in what circumstances. The configurations were used to refine components of the initial theoretical propositions against the evidence.

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## FINDINGS

### Phase 1

Evidence from 15 stakeholders was combined with literature on interventions aimed at improving healthcare for people living with dementia (22 papers) to generate three initial propositions for developing dementia-friendly hospital environments. Interventions described in the literature can be seen in table 1.

Table 1: Papers included in Phase 1

| Intervention | Papers |
|---|---|
| Schemes to identify people with dementia admitted to the ward: e.g. a butterfly symbol above patient's bed to help identify people who have dementia, linked to a training programme and the collection of biographical history from the family carer. | [39] |
| Dementia Champion: healthcare staff (mainly nursing staff) are trained to champion dementia care issues, providing support to peers. | [27, 40-44] |
| Dementia Specialist Nurse: senior nurse working across the hospital as an expert in dementia to advise staff on treatment, care practices, and liaise with community services. | [45, 46] |
| Staff training and education: training in dementia awareness and dementia care. | [9, 10, 28] |
| Liaison psychiatry / mental health teams: specialist teams working across the hospital to assess mental health of patients and advise staff on treatment and care. | [47, 48] |
| Environmental adaptions: changes to clinical areas including signage, new furniture, and improved flooring and lighting. | [15, 49] |
| Specialist units for people living with dementia: include physical adaptions and specialist staff to treat the medical and psychological needs of people living with dementia | [50-54] |
| Use of person centred care: model of care that prioritises the needs of the person. | [55] |

A key contextual factor to emerge from Phase 1 related to the role of change agents, although there were competing accounts of how a change agent might work and the

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responses they might trigger in staff. There appeared to be three distinct roles for change agents' activities that could lead to improved outcomes, these were:

- To support staff awareness and learning,
- To possess the authority to institute and sustain changes,
- To be a resource for staff as a clinical expert.

Change agent characteristics (e.g. supportive peer facilitator, organisational authority, clinical expertise) were considered to differently influence how staff engaged with interventions and this, in turn, would impact on patient outcomes (table 2).

Table 2: Initial theoretical propositions developed from phase 1

| Dementia-friendly interventions in hospitals improve outcomes for people living with dementia and their carers if… | Evidence from stakeholders and preliminary scoping and supporting references |
|---|---|
| … a change agent supports staff to reframe their understanding of dementia and respond appropriately to people living with dementia through learning and resources which address patient needs in an individual way. **Then** staff will have increased awareness of dementia and the impact dementia has on a person, and build confidence in their ability to recognise and address distress. | Emphasis on training and education that improve staff confidence in working with people living with dementia. Breaking down negative assumptions and supporting staff to see the person rather than the diagnosis. Use of resources to get to know the person.<br><br>References: [9, 10, 28, 39-42, 44, 55-57]<br><br>Stakeholders (SK01, SK02, SK03, SK04, SK05, SK06, SK07, SK09, SK10, SK11, SK12, SK13, SK14)<br>Example quote: "we're starting to do some training with our staff as well just to try and help everyone to know how to approach and how to feel empathy towards these patients who have dementia." (SK12) |
| … a change agent with organisational and clinical authority communicates the priorities for dementia care and addresses staff concerns | Strategic planning, prioritising good dementia care, providing resources that support staff to work in new ways, changes to systems and |

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| around managing risk and workplace disruption in person-centred ways. Staff are supported by training and resources that improve the involvement in decision-making and safety of people living with dementia, **then** staff will understand they have the permission and encouragement to adapt practices in ways that are beneficial for people living with dementia. | processes<br><br>References: [15, 42, 49-55]<br><br>Stakeholders (SK05, SK06, SK07, SK08, SK10, SK11, SK14, SK15)<br>Example quote: "…however good people's ideas are, if they don't have some kind of sign-off at a fairly senior level then they're not really going to have it 'cos they'll never be a priority and because there are so many targets to be met in general, unless there's some kind of strategy or policy in writing I don't think it can change much really." (SK08) |
| … a change agent with clinical expertise in dementia and dementia care supports staff with assessments and care planning **then** staff will identify and resolve the care needs of people living with dementia. | Assessments of cognition, mental health, and psychosocial needs. Role modelling good dementia care. Supporting staff to perform care in a person-centred way, direct care planning and address complex issues such as decisions of best interest, access to mental and social care information.<br><br>References: [45, 47, 48, 50-52, 58]<br><br>Stakeholders (SK04, SK09, SK11, SK14, SK15)<br>Example quote: "we had mental health nurses came to work with us and they had a really important part in role-modelling how it looked, how to approach things." (SK14) |

**Phase 2**

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Evidence from 28 papers, 12 of which were identified and included in phase one of the review (supplementary file 5), led to the development of six context-mechanism-outcome configurations (CMOCs) that explored the components of the three theoretical propositions developed in phase one (an overview of the selection process can be seen in Figure 1). These configurations are interconnected, representing key elements from the theories and how they relate to other factors (table 3). The CMOCs and supporting evidence are discussed below. Illustrative examples of evidence from the literature that guided CMOC development are supplied in Supplementary file 6.

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Table 3: Context-mechanism-outcome configurations and supporting evidence

| Brief title | Full Context-mechanism-outcome configuration | References |
|---|---|---|
| Understanding behaviour as communication to improve staffs' ability to respond | Where behaviours that challenge are understood as communication of an unmet need (context), through training, resources and support from experts in dementia care (mechanism resource), staff will feel they have improved capacity and capability to influence the situation (mechanism reasoning) making it more likely they will identify and address the need (outcome).<br>However<br>Conflicting work demands, patient characteristics (context) and staffing resources (mechanism resource), may lead staff to feel they are unable to make a difference (mechanism reasoning) meaning patient need might not be recognised, investigated or addressed (outcome) | [10, 15, 39, 40, 42, 45, 50, 52-55, 59-70] |
| The role of experiential learning and creating empathy to encourage reflection for responsibilities of care | Access to training (context) which promotes experiential learning and empathy towards people living with dementia (mechanism resource) can encourage reflection which identifies deficiencies in current working practices, helping staff to understand their responsibilities for care (mechanism reasoning), leading them to take more time with people living with dementia (outcome).<br>However<br>Where good dementia care practices (mechanism resource) are not considered legitimate working practices (context), staff may consider these | [10, 39, 40, 55, 59, 62-64] |

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| | practices as additional to their workload (mechanism reasoning) leading to inconsistent provision of care (outcome) | |
| Clinical experts who legitimise priorities for care | Clinical experts who have the authority to legitimise priorities and standards for dementia care endorsed by the organisation (context), provide support for staff to develop skills in dementia care (mechanism resource), can help staff feel confident of the expectations for their role (mechanism reasoning) to adapt working practices (outcome)<br>However<br>By focusing the responsibility for dementia care in select staff (context/mechanism resource), there may be a reduced sense of responsibility for dementia care in the wider workforce (mechanism reasoning) reducing the ability of experts to embed good dementia care practices across the organisation (outcome) | [40, 42, 45, 48, 50, 53-55, 59, 61-64, 69-71] |
| Staff with confidence to adapt working practices and routines to individualise care | Staff supported to be flexible in their role and working environment (context), where their responsibilities for patient care have been clarified (mechanism resource) may be responsive or adaptive in their decision making (mechanism reasoning) to provide care and treatment to a person in a timely, individualised manner (outcome)<br>However<br>Changes to staff capacity or environmental adaptions (context/mechanism resource) may need to be recognised and addressed by management (mechanism reasoning) to support staff to provide responsive care | [50, 55, 61, 62, 69] |

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| | | |
|---|---|---|
| | (outcome) | |
| Staff with responsibility to focus on psychosocial needs | Where there is provision of activities and therapies for people living with dementia that supports their interests and abilities (context) by staff with a role to address psychological, emotional and social issues (mechanism resource) and responsibility (mechanism reasoning) for maintaining functional and cognitive abilities, (outcome), this can provide other healthcare staff with time to prioritise physical and medical needs (outcome).<br>However<br>Where staffing resources are limited (context), staffing for activity and therapy can be reallocated to maintaining patient safety (mechanism resource) which may require staff to prioritising safety concerns (mechanism reasoning), limiting their ability to meet psychosocial needs (outcome). | [10, 50, 51, 54, 55, 62, 64, 65, 68, 70, 72] |
| Building staff confidence to provide person-centred risk management | Where procedures and expectations for care are set out to address risk in a person-centred way (context), and is encouraged and reinforced through ward leadership (mechanism resource) staff may feel confident to address risk proportionately (mechanism reasoning) and may support patients with dementia to maintain function and abilities in a less restrictive way. (outcome).<br>However<br>Resources will need to be compatible with environmental features and staff capacity (context/mechanism resource) or staff may not feel there is a value | [10, 15, 39, 50, 51, 53, 54, 64, 66-68, 70, 71] |

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| | to their work or for the patient (mechanism reasoning) making it unlikely they will adapt care practices (outcome) | |

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*CMOC 1. Understanding behaviour as communication to improve staffs' ability to respond*

Studies frequently reported that where staff understood behaviour that challenged as communication of an unmet need, they were more likely to investigate the underlying cause rather than attempting to control and restrict the behaviour [15, 40, 42, 53, 60, 66, 70]. By addressing the unmet need, staff reduced patient distress [50, 55, 59, 62, 63, 65, 70] and maintained independence, for example by supporting mobility and toileting needs [39, 54, 64, 69]. Inappropriate and negative staff responses arose from lack of understanding and misinterpretation of behaviours that challenge, for example, interpreting the patient as being deliberately difficult [52, 68].

Strategies employed to reframe staff understanding of behaviours included: training in dementia [10, 15, 55, 59, 62]; the use of biographical tools, completed in partnership with informal carers, [39, 40, 53, 67, 70]; assessments of cognition, pain, and psychological needs [50, 51, 54, 60]; and access to experts in dementia care [40, 42, 45, 50, 54, 70]. Common to these interventions were that they supported staff to consider potential causes of behaviours and provided strategies to address the unmet need, such as the development of individualised care plans [45, 67] and personalised strategies for reducing distress [39, 70]. Training to recognise behaviours as the expression of an unmet need [59, 61], and knowledge of a patient gained through continuity in their care [55, 61, 62] helped staff become aware that particular care practices were unsuitable and to adapt their work in a way that benefitted the individual. However, personalisation of practices appeared to occur in pockets of activity rather than as an ethos of care provision. Even when staff understood and were supported to work well with people living with dementia with behaviours that challenged, their ability and willingness to address psychological needs was limited. Conflicting work demands, staff fatigue, long shifts, and difficulty in identifying and resolving patient issues resulted in staff responding to behaviours by ignoring and disengaging from the patient [50, 65].

*CMOC 2. The role of experiential learning and creating empathy to encourage reflection for responsibilities of care*

Staff training that improved awareness of the impact of dementia and which addressed negative concepts was found to be a prerequisite for supporting good dementia care. While the literature suggested training had a positive impact on knowledge and confidence for

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working with people living with dementia, more work is need to understand how this works in practice [10, 39, 40, 59].

Training strategies which employed experiential learning techniques and cultivated empathy in staff for people living with dementia prompted reflection on current practices. Evidence suggested these training sessions produced 'lightbulb moments' for staff where they gained a sudden realisation of the problems faced by people living with dementia [40, 59, 64]. This appreciation for the importance to adapt care practices prompted staff to work in ways that would better support the patient, and improved staff satisfaction with their work [39, 72]. Additionally, one study reported how staff associated the portrayals of people living with dementia in training materials to their own relatives. This encouraged staff to see people living with dementia as individuals and motivated them to take responsibility to put their learning into practice [59].

The use of reflection and examples of good care practices in recognisable situations gave staff a framework for working well with people living with dementia and demonstrated the benefit to their own work [59, 64]. However, these practices were often referred to by staff as 'going the extra mile' or being additional to their workload rather than being an expectation of their role. Staff needed to be confident additional time spent with patients would not be viewed negatively by colleagues or impact on the requirements to manage the ward effectively, to support adaptions to care practices [55, 59].

*CMOC 3. Clinical experts who legitimise priorities for care*

Change agents influenced staff working practices through clinical expertise and organisational authority [40, 42, 45, 48, 50, 54, 62, 63, 70]. Experts in dementia care supported staff in the use of assessment tools and person-centred care planning [48, 54], role modelled appropriate behaviour and communication for working with people living with dementia [40, 50], and provided professional advice for complex situations, such as decisions around best interests [42, 45]. Access to experts in dementia care was suggested to reassure and encourage staff to provide good care for people living with dementia. Endorsement of these practices were communicated by clinical experts with a level of organisational authority at ward level [54, 55, 59, 62, 71] and across the organisation [53, 59, 63]. They addressed staff apprehensions to adaptions to care practices that previously prioritised medical and physical needs, ward routines, task focused ways of working, and organisational expectations for the completion of documentation and risk reduction [53, 54,

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62, 63, 71]. Our review found when change agents in authority communicated new expectations for standards of care and changes to procedures, they validated the priorities for care and legitimised staffs' adaption of care practices accordingly [53, 54, 59, 71]. However, the impact of changes to staffs' work needed to be recognised and supported [50, 53, 54, 62, 69-71]. For example, studies reported there was reduced capacity to work with previous levels of patient allocation [53, 62, 69], and changes to risk management strategies, such as encouraging mobility in a frail patient population at risk of falls, required staff training [54, 71].

There was limited evidence that new practices were adopted by staff and embedded into everyday practice directly through their contact with dementia experts. Instead, it appeared that the experts maintained responsibility for dementia care, either personally or by providing direction. The use of experts alone could potentially concentrate responsibility for dementia care in a small staff group rather than create a culture where all staff are responsible. Evidence from one paper [50] suggested that even when ward staff as a whole were better able to work with people living with dementia, they would defer issues unrelated to physical or medical healthcare to dementia experts.

*CMOC 4. Staff with confidence to adapt working practices and routines to individualise care*

The ability of staff to organise their work around the needs of people living with dementia rather than being restricted to the ward routine was linked to the provision of person-centred care [50, 55, 61, 62, 65, 69]. Where staff could incorporate getting to know the person, or recognise and respond directly to expressions of distress and unmet needs, patient wellbeing reportedly improved, evidenced through observations of positive mood [55, 61, 62, 65]. Clarity in staffs' responsibility for patient care was an important resource for improving their autonomy and encouraging them respond in timely, creative ways to meet individual needs [55, 61, 62].

Flexibility in working practices was suggested to be a factor in improving functional outcomes for people living with dementia. One study [69] attributed gains in mobility after hip surgery to therapy staff using their professional judgement to recognise optimal times that a person living with dementia would engage with a psychotherapy session, rather than risk the session being rejected. Additional factors that supported therapy staff to work flexibly included training in dementia care, reduced patient lists, and treatment rooms located on the ward [73].

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*CMOC 5. Staff with responsibility to focus on psychosocial needs*

Time constraints and staffing resources limited staff capacity to provide good dementia care. This was often addressed by employing staff with a specific role prioritising psychological, emotional and social needs through the use of cognitive and psychosocial assessments, therapeutic activities, supervising mealtimes, and managing risk [10, 50, 52, 54, 62, 65, 68]. The use of these staff and the activities they provided improved patient experience [62], assisted orientation to time and place [65], reduced distress [50, 62, 65], and reduced the onset of behaviours that challenged staff [50]. Studies reported how activities were sometimes deliberately scheduled to cover known times of high need within the patient population, such as during the afternoon when 'sun-downing' might occur [54] or when staffing levels were stretched, such as during mealtimes. For example, activities co-ordinators offered social dining opportunities where they could support conversations and prompt patients to eat [50, 62, 65, 70]. Although studies reported improved nutritional intake this was not formally evaluated.

Patients with more severe physical illness or cognitive impairment may not be able to participate in activities [50, 52] although it is possible they may have benefited indirectly as healthcare staff had more time to address their physical and medical needs. While this was referred to in two of the interviews, this was not explored in any of the papers.

Ward-wide staffing levels and skill mix impacted on staff ability to prioritise emotional, psychological and social needs [50, 62]. At times of staff shortages, ward management prioritised safety and managing risk over other non-medical needs [50, 62]. Risk management techniques, such as the use of 'specials' could be applied in a way that also addressed psychosocial needs. Two studies [50, 62] described how staff allocated to monitor patients at risk of falls engaged the patients in games, activities, and conversations. However, this was not always the case as staff assigned as 'specials' were often junior team members, had not received training in dementia care, and were unclear of the purpose of the role beyond monitoring the patient. This resulted in a lack of interaction with the patient and increased patient distress [68].

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*CMOC 6 Building staff confidence to provide person-centred risk management*

We found evidence that addressing risk in a way that supported a person's abilities, choices and independence improved mobility [54, 64], reduced adverse incidents [70], and improved patient and carer satisfaction [50, 53, 67]. Training, for example, on new skills and procedures for managing risk from change agents with clinical expertise and organisational authority, ensured staff understood the benefits to patients and had confidence to implement approved working practices [54, 67, 71]. Structural factors influenced the way risk was addressed. For example wards with locked door access meant patients could be monitored from a distance without restricting their movement around the ward [50, 53, 54, 66]; potentially leading to a reduction in behaviours that challenge as 'wandering' behaviours were no longer considered problematic.

In open wards, alternative methods were developed to easily identify patients considered at risk of leaving the ward, such as the use of wrist bands and different coloured hospital clothing, allowing staff to monitor them from a distance and intervene as necessary [10, 59, 64]. Identification methods were supported by staff training in the appropriate way to encourage a patient to return to their ward [10, 64].

**Refined programme theory**

From data in phase one we hypothesised that the existence of a change agent was important for improving hospital care for people living with dementia. However, work in phase two suggested that a reliance on single initiatives, such as a change agent, was insufficient to change staff behaviour. Additional contextual factors were also necessary in order for staff to make use of the resources interventions provided and use them in their practice with people living with dementia. The six context-mechanism-outcome configurations have been incorporated into a refined programme theory to suggest what needs to be in place to encourage best practice for dementia care in hospitals (figure 2). Figure 2 presents the programme theory. The preliminary CMOC suggests that resources which promote dementia awareness and an understanding of what constitutes 'good' dementia care are often initially implemented in situations where staff have limited understanding of how to provide care that addresses the needs of people living with dementia. These resources support staff to recognise the benefit of working well with patients with dementia and provides them with a common understanding of what good care looks like. This preliminary outcome then becomes part of the new context. Contextual factors, such as organisational endorsement of dementia care practices and clarity in staff

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responsibilities to patients with dementia, encourage staff to value resources, reinforcing improvements to care provision. It is anticipated that this will lead to improved patient outcomes, though evidence on outcomes was limited.

## DISCUSSION

Our review demonstrates how consideration of different contextual components in hospitals, hospital staff, and patients was fundamental to how the resources of an intervention might influence staff reasoning to adopt good dementia care practices. These changes in care practices may then lead to improved healthcare outcomes for people living with dementia. Developing an understanding in staff of the difficulties dementia presents for people with the condition helped them to recognise the need to approach care differently. Previous reviews of dementia care in hospital settings have identified training as an important strategy to improve staff knowledge of dementia and confidence to work well with people living with dementia, but have provided limited evidence for how this effects patient outcomes [29, 74, 75]. Findings from this review would suggest that training as a single strategy is not enough to influence staff to adapt the care they provide for people living with dementia. The culture of care within an organisation needs to support staff to provide good care for people living with dementia, legitimising practices so they are valued by staff. This means organisations need to recognise the impact this has on staff workload and roles and the changes that are necessary to ensure care provision can be adaptive to the needs of the patient. Staff needed to have a clear understanding of the expectation for care standards, and be confident that these changes are accepted by colleagues and senior staff if they are to improve the way care is provided for people living with dementia. Managerial endorsement for staff to work flexibly within their role, utilising practices and resources that enable them to get to know the person, will help staff to recognise and address signs of distress and implement best practice in dementia care.

Turner, et al. [74] suggests that to achieve the type of culture where person-centred care is valued, training in dementia should be aimed at a managerial level. Findings from this review would support their opinion; included studies where change agents in senior positions understood dementia and the associated impact on patient experience and care of the patient were reportedly able to positively influence the culture of care [53-55, 59, 63, 70, 72]. They communicated their vision for good dementia care, addressed processes within and between departments, provided resources that supported staffs' work, and considered the impact of changes to roles and responsibilities. However, even with this endorsement, there were still times, such as concerns for managing risk and resource shortages, where staff responsibilities were reorganised to prioritise physical over psychological wellbeing.

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Limited time and resources, and a preoccupation with managing risk are commonly cited factors that impacted on the ability of staff and organisations to sustain dementia-friendly hospital environments [29, 68, 74, 76, 77]. Employing staff who have a responsibility for the psychosocial needs of the patient can potentially improve patient experience of care while also making time available for nursing and medical staff to focus on physical and medical care needs of the patient. However, it is essential that contextual factors, such as staff awareness in dementia and dementia care, and staff clarification of their role and responsibilities are addressed before staffing resources are implemented into the setting. Moyle, et al. [68] demonstrated how the use of 'specials' without training in dementia care, a clear understanding of their role, and a prioritisation of risk management over addressing psychosocial needs resulted in poor outcomes for patients, such as increased agitation and reduced autonomy. A review on special observation [78] underlined the importance of clarity in the purpose of the role and adequately trained staff to optimise the role's therapeutic potential. Where responsibilities for care are assigned solely by the patient's symptoms this can lead to a narrow reactive approach to dementia care. Staff will still need to work as a team, rather than creating new tasks to focus on.

The initial aim of the review was to develop, test and refine a programme theory for how dementia-friendly interventions influence outcomes for people living with dementia during hospital admissions. However, testing the theory was problematic; evidence was limited, much was descriptive, there were few evaluations of interventions and approaches, and limited descriptions of setting and component parts of the interventions which impacted on the development of CMOC. Moreover, most studies included in the review reported little information around patient characteristics (e.g. type and severity of dementia) which meant we were unable to establish how the characteristics of people living with dementia interacted with the components of the interventions to influence outcomes. With these considerations, it is recognised that the proposed CMOCs were constrained by the evidence that was available and the inferences that could be made from the data; further development is needed.

Available evidence clustered around the training for staff and organisational support for changes to care practices. There was less evidence for how the introduction of staff providing activity and therapy for people living with dementia impacted on the practices of other staff. This review does, however, provide a programme theory that can be used as the basis for future evaluations. Our review also highlights the importance of focusing on patient

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related outcomes. It was clear from the initial interviews that whilst there was a shared understanding of the importance of dementia-friendly care, less attention has been paid to how different approaches enhanced patient outcomes. By focusing on outcomes as the basis for inclusion, this review addresses a knowledge gap about how different resources and approaches for dementia-friendly healthcare are effective for patients.

## CONCLUSION

The programme theory that has emerged from this review has the potential to improve how interventions to support dementia-friendly care in hospitals are designed and evaluated. The review highlights what needs to be in place to maximise the impact of training and the key characteristics for staff acting as change agents to influence colleagues to practice good dementia care. Specifically, the elements of interventions need to be relevant to provide ward staff with the awareness, authority, and resources to provide personalised care with support from staff with the relevant expertise. Educational interventions should focus on how staff can identify with the experience of being a patient living with dementia, combined with opportunities for staff to share their experiences of addressing challenges linked with the impact of dementia related behaviours on ward routines and priorities. This review provides a timely contribution and challenges the assumption that dementia awareness initiatives in acute care settings alone are sufficient to improve patient care.

## CONTRIBUTORS

MH led the design and prepared the review as part of her PhD (University of Hertfordshire, Hertfordshire, UK) and led manuscript preparation. FB and CG wrote the original funding application, supervised the review development, and critically reviewed manuscript drafts. All authors contributed to the debate and interpretation of data, read, and approved the final manuscript.

## AVAILABILITY OF DATA AND MATERIAL

All evidence cited in this review is available in the public domain. Data from the stakeholder interviews are not available to protect individuals' anonymity.

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## DISCLAIMER

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## COMPETING INTERESTS

The authors declare that they have no competing interests.

## ETHICS APPROVAL

Ethical approval for the interviews was secured from the University of Hertfordshire Ethics Committee (HSK/PG/UH/00339).

## CONSENT FOR PUBLICATION

Participants in stakeholder interviews consented to participation and the use of anonymised interview excerpts.

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For peer review only

## REFERENCES


1. Alzheimer's Society. Fix Dementia Care: Hospitals. London: Alzheimer's Society, 2016.
2. Alzheimer's Society. Counting the cost: Caring for people with dementia on hospital wards: Alzheimer's Society London, 2009.
3. Poblador-Plou BC-L, Amaia; Marta-Moreno, Javier; Hancco-Saavedra, Jorge; Sicras-Mainar, Antoni; Soljak, Michael; Prados-Torres, Alexandra. Comorbidity of dementia: a cross-sectional study of primary care older patients. *BMC psychiatry* 2014;**14**(1):84
4. Bunn FB, Ann-Marie; Goodman, Claire; Rait, Greta; Norton, Sam; Robinson, Louise; Schoeman, Johan; Brayne, Carol. Comorbidity and dementia: a scoping review of the literature. *BMC medicine* 2014;**12**(1):192
5. Royal College of Psychiatrists. Report of the national audit of dementia care in general hospitals 2011: Healthcare Improvement Quality Partnership, 2013.
6. Bunn F, Dickinson A, Simpson C, et al. Preventing falls among older people with mental health problems: a systematic review. *BMC nursing* 2014;**13**(1):4
7. Orsitto G, Fulvio F, Tria D, Turi V, Venezia A, Manca C. Nutritional status in hospitalized elderly patients with mild cognitive impairment. *Clinical Nutrition* 2009;**28**(1):100-02
8. Bail K, Goss J, Draper B, Berry H, Karmel R, Gibson D. The cost of hospital-acquired complications for older people with and without dementia; a retrospective cohort study. *BMC health services research* 2015;**15**(1):91
9. Elvish RB, Simon; Cawley, Rosanne; Harney, Kathryn; Graham, Pat; Pilling, Mark; Gregory, Julie; Roach, Pamela; Fossey, Jane; Keady, John. 'Getting to Know Me': the development and evaluation of a training programme for enhancing skills in the care of people with dementia in general hospital settings. *Aging & mental health* 2014;**18**(4):481-88
10. Galvin JEK, Barbara; Al-Hammadi, Noor; Germino, Jessica; Murphy-White, Maggie; McGillick, Janis. "Dementia-friendly hospitals: care not crisis" An educational program designed to improve the care of the hospitalized patient with dementia. *Alzheimer disease and associated disorders* 2010;**24**(4):372
11. Bunn F, Goodman C, Brayne C, et al. Comorbidity and dementia: improving healthcare for people with dementia. www. nets.nihr. ac. uk/projects/hsdr/11101707. NIHR, HS & DR, 2012.
12. White N, Leurent B, Lord K, Scott S, Jones L, Sampson EL. The management of behavioural and psychological symptoms of dementia in the acute general medical hospital: a longitudinal cohort study. *International Journal of Geriatric Psychiatry* 2016
13. Benbow SMJ, David. Dementia: stigma and its effects. *Neurodegenerative Disease Management* 2012;**2**(2):165-72
14. Swaffer K. Dementia: Stigma, Language, and Dementia-friendly. *Dementia* 2014;**13**(6):709-16 doi: 10.1177/1471301214548143published Online First: Epub Date]|.
15. Waller S, Masterson A. Designing dementia-friendly hospital environments. *Future Hospital Journal* 2015;**2**(1):63-68
16. Department of Health. Living Well with Dementia: a national dementia strategy. In: Health Do, ed. London, 2009.
17. Department of Health. Prime Minister's challenge on dementia 2020. In: Health Do, ed. London, 2015.
18. Health Education England. Dementia: Improving dementia care through effective basic training and continuous professional and vocational development. Secondary Dementia: Improving dementia care through effective basic training and continuous professional and vocational development 2016. https://www.hee.nhs.uk/our-work/hospitals-primary-community-care/mental-health-learning-disability/mental-health/dementia.
19. World Health Organization. Global age-friendly cities: A guide: World Health Organization, 2007.


For peer review only

20. Crampton J, Dean, J., Eley, R., AESOP Consortium. Creating a dementia-friendly York: Joseph Rowntree Foundation York, 2012.
21. Mitchell L, Burton E, Raman S. Dementia-friendly cities: Designing intelligible neighbourhoods for life. *Journal of Urban Design* 2004;**9**(1):89-101 doi: 10.1080/1357480042000187721published Online First: Epub Date]|.
22. Mitchell L, Burton E. Designing dementia-friendly neighbourhoods: helping people with dementia to get out and about. *Journal of Integrated Care* 2010;**18**(6):11-18
23. https://www.dementiafriends.org.uk/. Dementia Friends. Secondary Dementia Friends.
24. Joseph Rowntree Foundation. Developing a national user movement for people with dementia - learning from the Dementia Engagement and Empowerment Project (DEEP). 2015
25. Royal College of Nursing. Dementia: Commitment to the care of people with dementia in hospital settings. London, 2013.
26. Department of Health. Prime Minister's challenge on dementia: Delivering major improvements in dementia care and research by 2015. In: Health Do, ed. London, 2012.
27. Mayrhofer AG, C.; Holman, C. Establishing a community of practice for dementia champions (innovative practice). *Dementia (London, England)* 2014 doi: 10.1177/1471301214542534published Online First: Epub Date]|.
28. Mayrhofer A, Goodman C, Sharpe R, Dye H. Dementia Education in Hertfordshire and Bedfordshire: An organisational audit commissioned by Health Education East of England. Centre for Research in Primary and Community Care (CRIPACC), University of Hertfordshire. Hatfield: University of Hertfordshire, 2014.
29. Dewing JD, Saskia. What is the current state of care for older people with dementia in general hospitals? A literature review. *Dementia* 2014:1471301213520172
30. Pawson R. Evidence-based policy: A realist perspective: Sage publications, 2006.
31. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *BMC medicine* 2013;**11**(1):21
32. Dalkin SM, Greenhalgh J, Jones D, Cunningham B, Lhussier M. What's in a mechanism? Development of a key concept in realist evaluation. *Implementation Science* 2015;**10**(1):49
33. Pawson and Tilley. Realistic evaluation: Sage, 1997.
34. Handley M, Bunn F, Goodman C. Interventions that support the creation of dementia friendly environments in health care: protocol for a realist review. *Systematic reviews* 2015;**4**(1):1
35. Spencer; Ra. Qualitative data analysis for applied policy research. *The qualitative researcher's companion* 2002:305-29
36. Kitwood T, Bredin K. Evaluating dementia care the DCM method: Bradford, England: Bradford Dementia Research Group, Bradford University, 1997.
37. Wong G, Greenhalgh T, Pawson R. Internet-based medical education: a realist review of what works, for whom and in what circumstances. *BMC medical education* 2010;**10**(1):12
38. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review–a new method of systematic review designed for complex policy interventions. *Journal of health services research & policy* 2005;**10**(suppl 1):21-34
39. Williams R. Hospital programme for dementia-specific care: Using detailed observations of patients' experiences, Barbara Hodkinson developed the Butterfly Scheme to identify people with memory impairment and improve their care. She tells Ruth Williams how it works. *Nursing older people* 2011;**23**(7):14-17
40. Banks PW, A.; Henderson, J.; Sharp, B.; Brown, M.; Oliver, J.; Marland, G. Enriching the care of patients with dementia in acute settings? The Dementia Champions Programme in Scotland. *Dementia (London, England)* 2014;**13**(6):717-36 doi: 10.1177/1471301213485084published Online First: Epub Date]|.
41. Crabtree J, Mack J. Developing champions to enhance the care of people with dementia in general hospitals. *Nursing times* 2010;**106**(48):13-14

For peer review only

42. Ellison S, Watt G, Christie I. Evaluating the impact of the Alzheimer Scotland Dementia Nurse Consultants/Specialists & Dementia Champions in bringing about improvements to dementia care in acute general hospitals. 2014
43. Waugh AM, G.; Henderson, J.; Robertson, J.; Wilson, A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-9 doi: 10.7748/ns2011.04.25.32.44.c8452published Online First: Epub Date]|.
44. Wilkinson I, Coates A, Merrick S, Lee C. Junior doctor dementia champions in a district general hospital (innovative practice). *Dementia (London, England)* 2015 doi: 10.1177/1471301215584083published Online First: Epub Date]|.
45. Elliot R, Adams J. The creation of a Dementia Nurse Specialist role in an acute general hospital. *Journal of psychiatric and mental health nursing* 2011;**18**(7):648-52 doi: 10.1111/j.1365-2850.2011.01771.xpublished Online First: Epub Date]|.
46. Griffiths P, Bridges J, Sheldon H, Thompson R. The role of the dementia specialist nurse in acute care: a scoping review. *Journal of clinical nursing* 2014
47. Holmes J, Montaňa C, Powell G, et al. Liaison Mental Health Services for Older People: A Literature review, service mapping and in-depth evaluation of service models. *Produced for the National Institute for Health Research Service Delivery and Organisation programme* 2010
48. Baldwin R, Pratt H, Goring H, Marriott A, Roberts C. Does a nurse-led mental health liaison service for older people reduce psychiatric morbidity in acute general medical wards? A randomised controlled trial. *Age and ageing* 2004;**33**(5):472-78
49. Waller S. Redesigning wards to support people with dementia in hospital: Sarah Waller describes a programme that is bringing staff and patients together to create more welcoming and inspiring therapeutic environments. *Nursing older people* 2012;**24**(2):16-21
50. Goldberg S, Whittamore KH, Pollock K, Harwood RH, Gladman JR. Caring for cognitively impaired older patients in the general hospital: a qualitative analysis of similarities and differences between a specialist Medical and Mental Health Unit and standard care wards. *Int J Nurs Stud* 2014;**51**(10):1332-43 doi: 10.1016/j.ijnurstu.2014.02.002published Online First: Epub Date]|.
51. Goldberg S, Bradshaw, Lucy E; Kearney, Fiona C; Russell, Catherine; Whittamore, Kathy H; Foster, Pippa ER; Mamza, Jil; Gladman, John RF; Jones, Rob G; Lewis, Sarah A. Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial). *BMJ (Clinical research ed.)* 2013;**347**
52. Spencer K, Foster, P., Whittamore, K. H., Goldberg, S. E., Harwood, R. H. Delivering dementia care differently--evaluating the differences and similarities between a specialist medical and mental health unit and standard acute care wards: a qualitative study of family carers' perceptions of quality of care. *BMJ open* 2013;**3**(12):e004198 doi: 10.1136/bmjopen-2013-004198published Online First: Epub Date]|.
53. Nichols JN, Heller KS. Windows to the heart: Creating an acute care dementia unit. *Journal of palliative medicine* 2002;**5**(1):181-92
54. Zieschang T, Dutzi I, Müller E, et al. Improving care for patients with dementia hospitalized for acute somatic illness in a specialized care unit: a feasibility study. *International Psychogeriatrics* 2010;**22**(01):139-46
55. Scerri A, Innes A, Scerri C. Discovering what works well: exploring quality dementia care in hospital wards using an appreciative inquiry approach. *Journal of clinical nursing* 2015
56. Waugh A, Marland G, Henderson J, Robertson J, Wilson A. Improving the care of people with dementia in hospital. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)* 2011;**25**(32):44-49

For peer review only

57. Mayrhofer A, Goodman C, Holman C. Establishing a community of practice for dementia champions (innovative practice). *Dementia* 2015;**14** doi: 10.1177/1471301214542534published Online First: Epub Date]|.
58. Griffiths A, Knight A, Harwood R, Gladman JR. Preparation to care for confused older patients in general hospitals: a study of UK health professionals. *Age and ageing* 2013:aft171
59. Baillie L. An Evaluation of Barbara's Story: Final Report. London: Guy's and St Thomas' NHS Foundation Trust, London South Bank University, 2015.
60. Dowding D, Lichtner V, Allcock N, et al. Using sense-making theory to aid understanding of the recognition, assessment and management of pain in patients with dementia in acute hospital settings. *International Journal of Nursing Studies* 2016;**53**:152-62
61. Schneider J, Scales K, Bailey S, Lloyd J. Challenging care: the role and experience of health care assistants in dementia wards. *National Institute for Health Research Service Delivery and Organisation programme. Available online at http://panicoa. org. uk/sites/assets/challenging_care. pdf [Accessed August]* 2010
62. Bray J, Evans S, Bruce M, et al. Improving activity and engagement for patients with dementia. *Nursing older people* 2015;**27**(8):22
63. Brooker DM, Sarah; Evans, Simon; Carter, Christine; Bruce, Mary; Thompson, Rachel. RCN Development Programme: Transforming Dementia Care in Hospitals Evaluation Report. 2014
64. Duffin C. Raising awareness to support people with dementia in hospital: A film produced to train staff at one trust has had such a positive effect that it is to be used nationwide. Christian Duffin reports on this and other measures to improve care. *Nursing older people* 2013;**25**(5):14-17
65. Edvardsson D, Sandman PO, Rasmussen B. Forecasting the ward climate: a study from a dementia care unit. *Journal of clinical nursing* 2012;**21**(7-8):1136-114
66. Gonski PN, Moon I. Outcomes of a behavioral unit in an acute aged care service. *Archives of gerontology and geriatrics* 2012;**55**(1):60-65
67. Luxford K, Axam A, Hasnip F, et al. Improving clinician–carer communication for safer hospital care: a study of the 'TOP 5'strategy in patients with dementia. *International Journal for Quality in Health Care* 2015:mzv026
68. Moyle W, Borbasi S, Wallis M, Olorenshaw R, Gracia N. Acute care management of older people with dementia: a qualitative perspective. *Journal of clinical nursing* 2011;**20**(3-4):420-28
69. Rösler A, von Renteln-Kruse W, Mühlhan C, Frilling B. Treatment of dementia patients with fracture of the proximal femur in a specialized geriatric care unit compared to conventional geriatric care. *Zeitschrift für Gerontologie und Geriatrie* 2012;**45**(5):400-03
70. Upton. An evaluation of quality and cost effectiveness of a newly defined suite of care interventions for patients with dementia and their carers in the acute hospital setting developed by The Royal Wolverhampton Hospitals NHS Trust REPORT PHASE 2 – Volume 1: University of Worcester, 2012.
71. Enns E, Rhemtulla R, Ewa V, Fruetel K, Holroyd-Leduc JM. A controlled quality improvement trial to reduce the use of physical restraints in older hospitalized adults. *Journal of the American Geriatrics Society* 2014;**62**(3):541-45 doi: 10.1111/jgs.12710published Online First: Epub Date]|.
72. Harwood RH PD, King N, Edwards G, Hammond S, Howe L, et al. . Development of a Specialist Medical and Mental Health Unit for Older People in an Acute General Hospital. MedicalCrises in Older People Discussion Paper Series. Issue 5, November 2010., 2010.
73. von Renteln-Kruse W, Neumann L, Klugmann B, et al. Geriatric Patients With Cognitive Impairment: Patient Characteristics and Treatment Results on a Specialized Ward. *Deutsches Ärzteblatt International* 2015;**112**(7):103
74. Turner A, Eccles FJ, Elvish R, Simpson J, Keady J. The experience of caring for patients with dementia within a general hospital setting: a meta-synthesis of the qualitative literature. *Aging & mental health* 2015:1-11

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75. Digby R, Lee S, Williams A. Interviewing people with dementia in hospital: recommendations for researchers. *Journal of clinical nursing* 2016
76. Digby R, Lee S, Williams A. The experience of people with dementia and nurses in hospital: an integrative review. *Journal of clinical nursing* 2016
77. Borbasi S, Jones J, Lockwood C, Emden C. Health Professionals' Perspectives of Providing Care to People with Dementia in the Acute Setting: Toward Better Practice. *Geriatric Nursing* 2006;**27**(5):300-08 doi: 10.1016/j.gerinurse.2006.08.013published Online First: Epub Date]|.
78. Dewing J. Special observation and older persons with dementia/delirium: a disappointing literature review. *International journal of older people nursing* 2013;**8**(1):19-28

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Figure legends

Figure 1: Flow diagram of searches and evidence retrieval

Figure 2: Refined programme theory: CMOC for best practice for care of people living with dementia admitted to hospital

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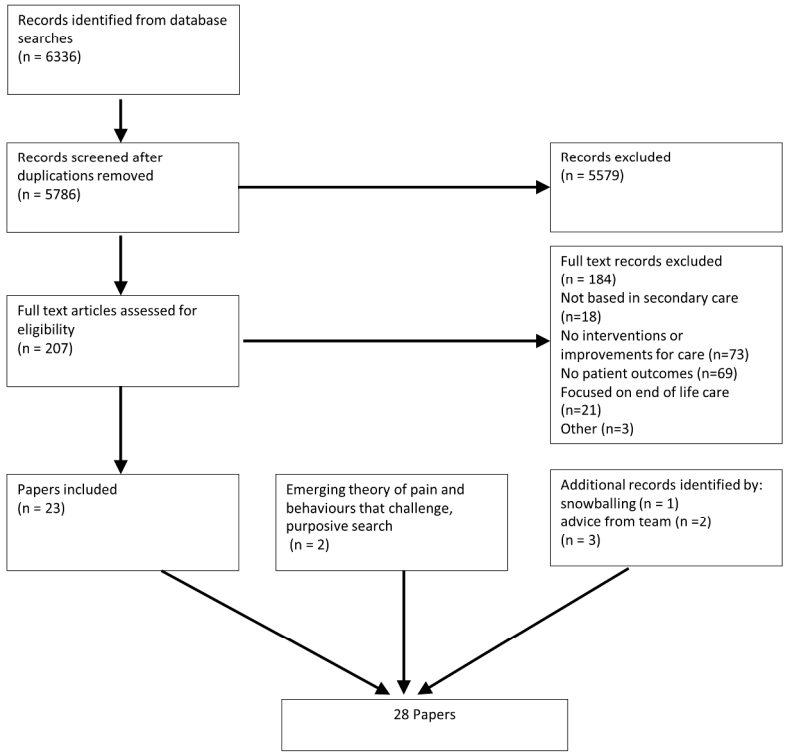


Figure 1: Flow diagram of searches and evidence retrieval

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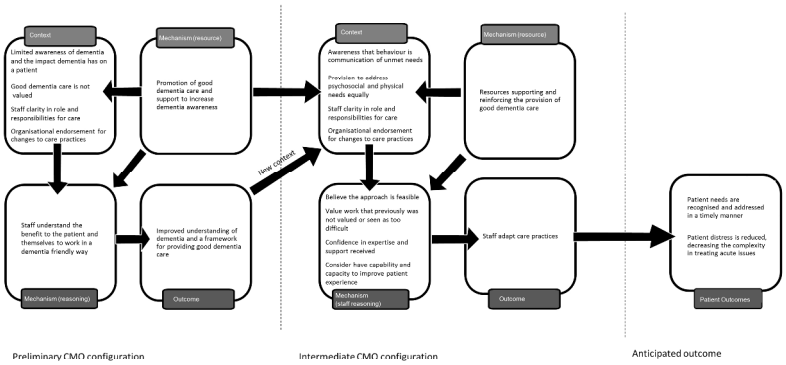


Figure 2: Refined programme theory: CMO configurations for best practice for care of people living with dementia admitted to hospital

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# RAMESES publication standards: realist syntheses

Geoff Wong[1*], Trish Greenhalgh[1], Gill Westhorp[2], Jeanette Buckingham[3] and Ray Pawson[4]

## Abstract

**Background:** There is growing interest in realist synthesis as an alternative systematic review method. This approach offers the potential to expand the knowledge base in policy-relevant areas - for example, by explaining the success, failure or mixed fortunes of complex interventions. No previous publication standards exist for reporting realist syntheses. This standard was developed as part of the RAMESES (Realist And MEta-narrative Evidence Syntheses: Evolving Standards) project. The project's aim is to produce preliminary publication standards for realist systematic reviews.

**Methods:** We (a) collated and summarized existing literature on the principles of good practice in realist syntheses; (b) considered the extent to which these principles had been followed by published syntheses, thereby identifying how rigor may be lost and how existing methods could be improved; (c) used a three-round online Delphi method with an interdisciplinary panel of national and international experts in evidence synthesis, realist research, policy and/or publishing to produce and iteratively refine a draft set of methodological steps and publication standards; (d) provided real-time support to ongoing realist syntheses and the open-access RAMESES online discussion list so as to capture problems and questions as they arose; and (e) synthesized expert input, evidence syntheses and real-time problem analysis into a definitive set of standards.

**Results:** We identified 35 published realist syntheses, provided real-time support to 9 on-going syntheses and captured questions raised in the RAMESES discussion list. Through analysis and discussion within the project team, we summarized the published literature and common questions and challenges into briefing materials for the Delphi panel, comprising 37 members. Within three rounds this panel had reached consensus on 19 key publication standards, with an overall response rate of 91%.

**Conclusion:** This project used multiple sources to develop and draw together evidence and expertise in realist synthesis. For each item we have included an explanation for why it is important and guidance on how it might be reported. Realist synthesis is a relatively new method for evidence synthesis and as experience and methodological developments occur, we anticipate that these standards will evolve to reflect further methodological developments. We hope that these standards will act as a resource that will contribute to improving the reporting of realist syntheses.

To encourage dissemination of the RAMESES publication standards, this article is co-published in the Journal of Advanced Nursing and is freely accessible on Wiley Online Library (http://www.wileyonlinelibrary.com/journal/jan).

Please see related article http://www.biomedcentral.com/1741-7015/11/20 and http://www.biomedcentral.com/1741-7015/11/22

**Keywords:** realist synthesis, realist review, publication standards

## Background

Academics and policymakers are increasingly interested in 'policy-friendly' approaches to evidence synthesis. Such approaches seek to illuminate issues and understand contextual influences on whether, why and how interventions might work [1,2]. A number of different approaches have been used to try to achieve this goal. At present there is lack of clarity on which methods are best suited for which questions or problems and this has been the subject of debate [3-6] and further research [7]. Realist synthesis is a theory-driven approach that is becoming increasingly popular.

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### What is a realist synthesis?

In this section we briefly describe the realist synthesis method. The realist research question is often summarized as "What works for whom under what circumstances, how and why?" Realist inquiry is based on a realist philosophy of science and considers the interaction between context, mechanism and outcome. From a realist perspective, intervention X is not thought of as having effect size Y with confidence interval Z. Rather, intervention X (for example, a program introduced by policymakers who seek to create a particular outcome) alters context (for example, by making new resources available), which then triggers mechanism(s), which produce both intended and unintended outcomes. Intervention X may work well in one context but poorly or not at all in another context.

Realist inquiry seeks to unpack the context - mechanism - outcome relationship, thereby explaining examples of success, failure and various eventualities in between. Theoretical explanations of this kind are referred to as "middle-range theories" (that is, ones which "...involve abstraction... but [are] close enough to observed data to be incorporated in propositions that permit empirical testing" [8].

The basis of realist inquiry is a realist philosophy, whose key tenets are as follows:

1. There is a [social] reality that cannot be measured directly (because it is processed through our brains, language, culture and so on), but can be known indirectly.

Realism thus sits, broadly speaking, between positivism ('there is a real world which we can apprehend directly through observation') and constructivism ('given that all we can know has been interpreted through human senses and the human brain, we cannot know for sure what the nature of reality is').

2. Social programs (including complex interventions) may change the macro social context (for example, by introducing legislation). They may also change the resources or opportunities available to participants and, in that sense, change the meso- or micro-level context for those participants.

3. To understand the relationship between context and outcome, realism uses the concept of mechanisms, one definition of which is "...underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest" [9].

In common with other theory-driven review methods, the realist approach offers the potential for insights that go beyond the narrowly experimental paradigm of the randomized controlled trial [10-12]. It can do so in relation to complex, complicated or simpler interventions (for example, even a simple intervention, such as a drug, is prescribed, dispensed and taken - or not - in a particular social, cultural and economic context).

"Realist synthesis" was first described by Ray Pawson in 2002 [13], updated in an ESRC (Economic and Social Research Council) commissioned monograph in 2004 [14], published as a book in 2006 [1] and summarizsed in a short methods paper in 2005 [15]. Since this paper is deliberately focused on publication standards, we strongly recommend that those unfamiliar with the realist approach consult these or other relevant methodological sources.

A realist synthesis (or realist review - these terms are synonymous) applies realist philosophy to the synthesis of findings from primary studies that have a bearing on a single research question or set of questions. Methodologically, reviewers may begin by eliciting from the literature the main ideas that went into the making of a class of interventions (the program theory). This program theory sets out how and why a class of intervention is thought to 'work' to generate the outcome(s) of interest. The pertinence and effectiveness of each constituent idea is then tested using relevant evidence (qualitative, quantitative, comparative, administrative and so on) from the primary literature on that class of programs. In this testing, the ideas within a program theory are re-cast and conceptualized in realist terms.

For each idea, reviewers seek out the contextual (C) influences that are hypothesized to have triggered the relevant mechanism(s) (M) to generate the outcome(s) (O) of interest. Synthesis consists of comparing 'how the programme was supposed to operate' to the 'empirical evidence on the actuality in different situations' - all along C-M-O lines. Analytic purchase comes from the ability to describe and understand the many contingencies that affect the likelihood of such interventions generating their intended outcomes. This in turn provides guidance about what policy makers or practitioners might put in place to change the context or provide resources in such a way as to most likely trigger the right mechanism(s) to produce the desired outcome.

### Why are publication standards needed?

Publication standards are common (and, increasingly, expected) - in health services research - see, for example, CONSORT for randomized controlled trials [16], AGREE for clinical guidelines [17], PRISMA for Cochrane-style systematic reviews [18] and SQUIRE for quality improvement studies [19]. For realist syntheses, publication standards are particularly important as this method is relatively new and concerns have been expressed about the rigor with which some realist reviews have been carried out and reported [20]. Publication standards are needed to ensure that users of reviews are provided with relevant and necessary information to enable them to assess the quality and rigor of a review.

In our experience, there is considerable confusion among researchers, journal editors, peer reviewers and

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funders about what counts as a high quality realist review and what, conversely, counts as a flawed review. Even though experts still differ on detailed conceptual methodological issues, the increasing popularity of this method prompted a study to develop baseline standards from which, we anticipate, further developments in theory and methodology of this approach will occur.

## Aim

The aim of this paper is to produce preliminary publication standards for realist syntheses.

## Methods

The methods we used to develop these reporting standards have already been published [20]. In brief, we purposively recruited an international group of experts to our online Delphi panel. Aiming to achieve maximum variety in the relevant sectors, disciplines and expert perspectives represented, we sought panel members working in realist research, evidence synthesis, publication, reviewer training and health policy. Prior to the start of our Delphi panel, with input from an expert informaticist (JB), we collated and summarized existing literature on the principles of good practice in realist synthesis, created a database of such published syntheses, and built relationships with teams who were undertaking ongoing syntheses. Through discussion within the project team, we considered the extent to which the principles had been followed by published and in-progress reviews, thereby identifying how rigor may be lost and how existing methods could be improved.

Our analysis of existing realist syntheses formed the basis of the briefing materials for the first round of the Delphi panel. In addition, we drew on our collective experience in training and supporting realist syntheses teams and an email discussion list on realist and meta-narrative methodology [21] to further inform the contents of our briefing document. Both the research team and panel members contributed draft items for the publication standards, and these were refined using the online Delphi process as previously described [20]. We ran the Delphi panels between September 2011 and March 2012.

### Description of panel and items

In all, we recruited 37 individuals from 27 organizations in 6 countries. These comprised: researchers in public or population health researchers (8); evidence synthesis (6); health services research (8); international development (2); education (2); and also research methodologists (6), publishing (1), nursing (2) and policy and decision making (2). In round 1, 22 Delphi panel members provided suggestions of items that should be included in the publication standards. In rounds 2 and 3 our panel members were asked to rate each potential item for relevance and clarity. The response rates across all items for rounds 2 and 3 were 93% and 89%, respectively. Consensus was reached within three rounds on both the content and wording of 19 items within the publication standards. Table 1 provides an overview of these items.

### Scope of the publication standards

These publication standards are intended to help researchers, authors, journal editors, and policy and decision makers to know and understand what should be reported in the write-up of a realist synthesis. They are not intended to provide detailed guidance on how to conduct such a synthesis; for this, we direct interested readers to summary articles [15,22] or various publications on methods [1,11,14,23]. This publication standard applies only to realist syntheses. A list of publication guidelines for other review methods can be found on the EQUATOR Network's website [24], but at present none of these relate specifically to realist syntheses. As part of the RAMESES project we are also developing quality standards and training materials for realist syntheses, which will be submitted as a separate publication. Publication standards for meta-narrative reviews (also covered in the RAMESES project) have been addressed in a separate article.

### How to use these publication standards

The layout of this document has drawn on previous methodological publications and, in particular, on the 'Explanations and Elaborations' document of the PRISMA statement [18]. Each item is followed by an example drawn from published reviews and a rationale for its inclusion. The purpose of the example text is to illustrate how an item might be reported in a write up. However, potentially relevant contextual information may have been omitted, so it may be necessary to consult the original paper from which the example text was drawn. The standards set out what might be expected for each item, but authors will still need to exercise judgement about how much information to include. The purpose of the details reported should be to ensure that the description and explanation provided is coherent and plausible, both against the guidance set out within an item and for the overall purpose of the realist synthesis.

While this publication standard is modeled on the PRISMA statement, the items within are not identical. This publication standard, developed to apply only to realist syntheses, has some overlap with the PRISMA statement. Items 1 to 3, 15, 16 and 19 in this statement broadly match the purpose of items 1 to 3, 24, 25 and 27 in the PRISMA statement. For items 4 to 14, while there is some overlap in purpose with some PRISMA statement items, different or additional reporting is needed due to the nature of realist syntheses. Other items (5, 12, 13, 15, 16, 19

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**Table 1 List of items to be included when reporting a realist synthesis**

| | | |
|---|---|---|
| **TITLE** | | |
| 1 | | In the title, identify the document as a realist synthesis or review |
| ABSTRACT | | |
| 2 | | While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice. |
| INTRODUCTION | | |
| 3 | Rationale for review | Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area. |
| 4 | Objectives and focus of review | State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review. |
| METHODS | | |
| 5 | Changes in the review process | Any changes made to the review process that was initially planned should be briefly described and justified. |
| 6 | Rationale for using realist synthesis | Explain why realist synthesis was considered the most appropriate method to use. |
| 7 | Scoping the literature | Describe and justify the initial process of exploratory scoping of the literature. |
| 8 | Searching processes | While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected. |
| 9 | Selection and appraisal of documents | Explain how judgements were made about including and excluding data from documents, and justify these. |
| 10 | Data extraction | Describe and explain which data or information were extracted from the included documents and justify this selection. |
| 11 | Analysis and synthesis processes | Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process. |
| RESULTS | | |
| 12 | Document flow diagram | Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example templates (which are likely to need modification to suit the data) that are provided. |
| 13 | Document characteristics | Provide information on the characteristics of the documents included in the review. |
| 14 | Main findings | Present the key findings with a specific focus on theory building and testing. |
| DISCUSSION | | |
| 15 | Summary of findings | Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s). |
| 16 | Strengths, limitations and future research directions | Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged.<br>The limitations identified may point to areas where further work is needed. |
| 17 | Comparison with existing literature | Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic. |
| 18 | Conclusion and recommendations | List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice. |
| 19 | Funding | Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers. |

and 23) in the PRIMSA statement have no equivalent in the RAMESES publication standards for realist reviews.

The order in which items are reported may vary. Realist syntheses are not 'linear' reviews. Some of the processes that are listed may legitimately take place in parallel or have to be revisited at a later date as a review progresses. As a general rule, if a recommended item is excluded from the write-up of a realist synthesis, a justification should be provided.

### The RAMESES publication standards for realist syntheses

#### *Item 1: Title*

In the title, identify the document as a realist synthesis or review.

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**Example**

"Human resource management interventions to improve health workers' performance in low and middle income countries: a realist review." [25]

**Explanation**

Our background searching has shown that some realist reviews are not flagged as such in the title and may also be inconsistently indexed and, hence, are more difficult to locate during searching. The terms 'realist synthesis' and 'realist review' are both in widespread use. We asked our Delphi panel if they had a preferred term - 'realist synthesis' or 'review'. No consensus was reached by our Delphi panel on whether 'review' or 'synthesis' should be the preferred term, and there seemed no good reason to impose one or other term.

***Item 2: Abstract***

While acknowledging that requirements and house style may differ between journals, abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.

**Example**

***"Background***

Legislation is one of the most powerful weapons for improving population health and is often used by policy and decision makers. Little research exists to guide them as to whether legislation is feasible and/or will succeed. We aimed to produce a coherent and transferable evidence based framework of threats to legislative interventions to assist the decision making process and to test this through the 'case study' of legislation to ban smoking in cars carrying children.

***Methods***

We conceptualised legislative interventions as complex social interventions and so used the realist synthesis method to systematically review the literature for evidence. 99 articles were found through searches on five electronic databases (MEDLINE, HMIC, EMBASE, PsychINFO, Social Policy and Practice) and iterative purposive searching. Our initial searches sought any studies that contained information on smoking in vehicles carrying children. Throughout the review we continued where needed to search for additional studies of any type that would conceptually contribute to helping build and/or test our framework.

***Results***

Our framework identified a series of transferable threats to public health legislation. When applied to smoking bans in vehicles; problem misidentification, public support; opposition; and enforcement issues were particularly prominent threats. Our framework enabled us to understand and explain the nature of each threat and to infer the most likely outcome if such legislation were to be proposed in a jurisdiction where no such ban existed. Specifically, the micro-environment of a vehicle can contain highly hazardous levels of second hand smoke. Public support for such legislation is high amongst smokers and non-smokers and their underlying motivations were very similar - wanting to practice the Millian principle of protecting children from harm. Evidence indicated that the tobacco industry was not likely to oppose legislation and arguments that such a law would be 'unenforceable' were unfounded.

***Conclusion***

It is possible to develop a coherent and transferable evidence based framework of the ideas and assumptions behind the threats to legislative intervention that may assist policy and decision makers to analyse and judge if legislation is feasible and/or likely to succeed." [26]

**Explanation**

Apart from the title, an abstract is the only source of information accessible to searchers unless the full paper is obtained. The information in it must allow reviewers and/or users to decide if the review is relevant to their needs.

**Introduction section**

The following items should be reported in the introduction section.

***Item 3: Rationale for review***

Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.

**Example**

"A number of reviews on the subject have tried to examine evidence to improve the operationalization of interventions by CHWs [community health workers], including for child health. Lehmann *et al.* (Reference x1) and Lewin *et al.* (Reference x1) have reviewed evidence on CHW interventions in LMIC [low-middle income countries] and Haines *et al.* (Reference x1) have particularly so for child health. Lewin *et al.* (Reference x1) found lay health workers to be effective in specific areas in child health, when compared to usual care. Haines *et al.* (Reference x1) highlight the contextual nature of CHW's performance. Both caution that CHW interventions are not the panacea for all that ails the health systems in LMIC and that large scale CHW programmes should be initiated with great caution. Both raise questions about the applicability of findings to different settings and about the conditions under which CHW interventions should be implemented." [27]

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**Explanation**

As with all research, a background section explaining what is already known and what the researchers considered to be the 'knowledge gaps' is a helpful orientation.

***Item 4: Objectives and focus of review***

State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.

**Example**

"The overriding question for the review was: Does moving from high-poverty neighborhoods to lower-poverty neighborhoods improve health? More specifically: What were the key health outcomes? Who experienced these outcomes? What appeared to be the mechanisms and associated context leading to the outcomes? As the review proceeded, it became clear that one of the only relatively consistent and statistically significant positive health outcomes was an improvement in mental health for adult women, children and adolescent girls. In this paper a review of mental health outcomes of MTO [Moving To Opportunity] is presented, along with some insights about the mechanisms and contexts through which the intervention appears to have impacted mental health." [28]

**Explanation**

A realist research question contains some or all of the elements of 'What works, how, why, for whom, to what extent and in what circumstances, in what respect and over what duration?' and applies realist logic to address the question (see Item 11).

Because a realist synthesis may generate a large number of avenues that might be explored and explained, and because resources and timescale are invariably finite, the expectation is that the review must be 'contained' by progressively focusing both its breadth (how wide an area?) and depth (how much detail?). This important process may involve discussion and negotiation with, for example, content experts, funders and/or users. It is typical and legitimate for the synthesis' objectives, question and/or the breadth and depth of the review to evolve as the review progresses. How and why it evolved is usually worth reporting.

**Methods section**

The following items should be reported in the methods section.

***Item 5: Changes in the review process***

Any changes made to the review that was initially planned should be briefly described and justified.

**Example**

"As the review progressed we became aware of various data suitability limitations (see Discussion) and the emergence of two prominent demi-regularities prompted us to narrow our review focus to the two candidate theories discussed below." [29]

**Explanation**

A realist synthesis can (and, in general, should) evolve over the course of the review. For example, changes to the research question or its scope are likely to have an impact on many of the synthesis' subsequent processes. However, this does not mean the synthesis can meander uncontained. An accessible summary of what was originally planned (for example, as described in an initial protocol) and how and why this differed from what was done should be provided as this may assist interpretation.

***Item 6: Rationale for using realist synthesis***

Explain why realist synthesis was considered the most appropriate method to use.

**Example**

"Previous reviews sought to understand PR [participatory research] and provide practical recommendations (References x6) and to assess the value of PR to research goals, health status, and systems change (References x6). Nonetheless, the assessment of outcomes remains weak (Reference x4), partly because the methodologies used have generally failed to embrace the complexity of programs or address mechanisms of change (Reference x1). ...

To handle such complexity, we chose a realist approach (Reference x1) because it provides a rationale and tools for synthesizing complex, difficult-to-interpret evidence from community-based programs." [30]

**Explanation**

Realist synthesis is a theory-driven method that is firmly rooted in a realist philosophy of science. It places particular emphasis on understanding causation (in this case, understanding how programs and policies generate outcomes through human decisions) and how causal mechanisms are shaped and constrained by social context. This makes it particularly suitable for reviews of certain topics and questions - for example, complex social programs that involve human decisions and actions. It also makes realist synthesis *less* suitable than other review methods for certain topics and questions - for example, those which seek primarily to determine the average effect size of a simpler intervention administered in a single or limited range of conditions. In our analysis of 37 published realist syntheses, the most common limitation was inadequate engagement with realist explanatory principles and the implications these have, first, for understanding programs and how they work, and second, for cumulating evidence and explanation.

Some realist syntheses published to date have deliberately adapted the method as first described by Pawson.

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Sometimes, adaptations may be entirely justifiable, but at other times they may indicate a poor grasp of realist methodology. To enable judgement to be made on adaptations, the description and rationale for adaptations should be provided. Such information will allow criticism, debate and counter criticism among review teams and users on the suitability of such adaptations, and may well facilitate methodological development.

***Item 7: Scoping the literature***

Describe and justify the initial process of exploratory scoping of the literature.

**Example**

"To develop our framework on the threats to the programme theory of public health legislation we started out by conducting a rapid review of broad areas of public health legislation (covering everything from gun amnesties to food labelling) trying to uncover what had been the sticking points in legislation and how (if at all) they had been circumvented. This outline review led to the construction of a provisional framework for reviewing the family of legislative interventions (as described in Figure 1). .... . Beginning with this framework and through discussions (and with reference to other interested stakeholders) we focused on a subset of themes that seemed most relevant in respect to the intervention in question. In our case, we deliberately sought input from the NICE officer seconded to our project." [26]

**Explanation**

This step is used to build an understanding of the topic area. For example, this step may be used to identify provisional program theories, the names/titles of programs within scope and key authors in the area. Initial attempts to make sense of a topic area may involve informal 'browsing' of the literature and also consulting with experts and stakeholders.

***Item 8: Searching process***

While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.

**Example**

"...the literature search was iterative and ongoing throughout the project. An initial search was conducted of various academic databases, such as Academic Search Premier, Arts and Humanities Citation Index, Canadian Research Index, as well as through various search engines, such as Prowler, Novanet, Google and Google Scholar. Search terms included: Moving to Opportunity [MTO]; housing intervention; housing mobility; housing health effects; low-

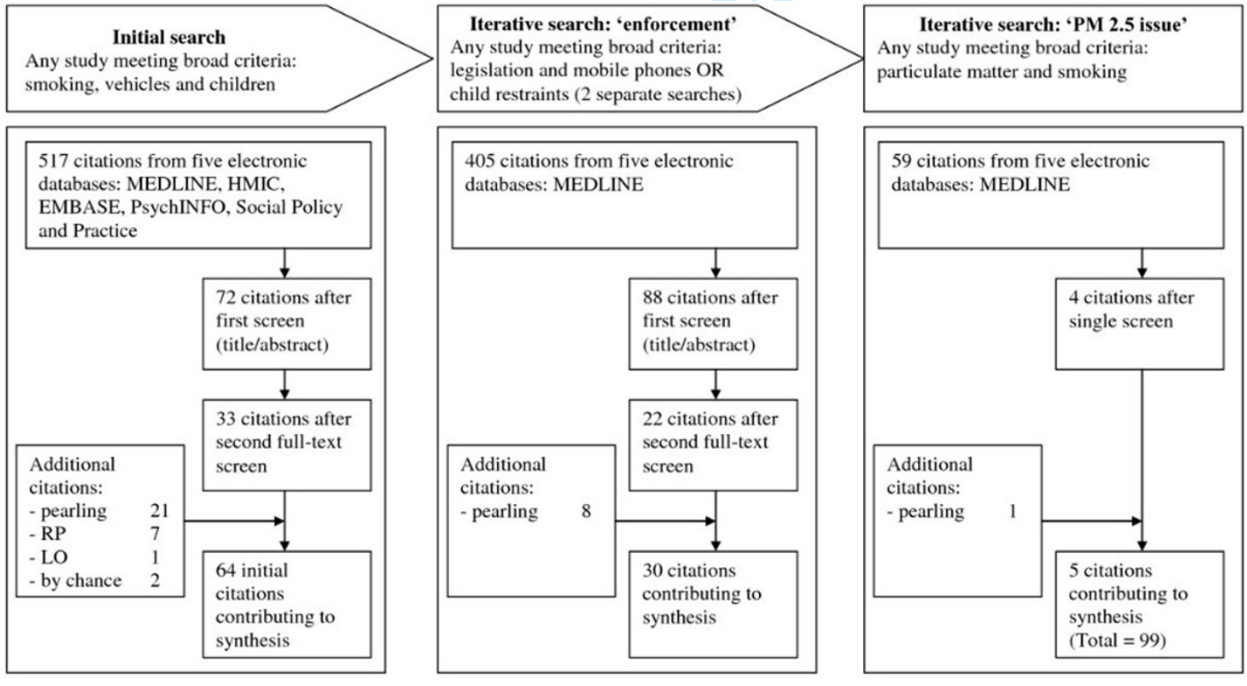


**Figure 1** Flow diagram illustrating search process and article disposition [26].

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poverty neighborhood/community; high-poverty neighborhood/community; neighborhood/community health; poverty neighborhood/community; poverty community effects; poverty housing; poverty health; and housing health. A "snowball" approach was used in which one reference led to others. Other evaluations were revealed through correspondence with Dr. Jeffrey Kling, one of the principal MTO researchers." [28]

**Explanation**

Searching should be guided by the objectives and focus of the synthesis, and revised iteratively in the light of emerging data. Data relevant to a realist synthesis may lie in a broad range of sources that may cross traditional disciplinary, program and sector boundaries. The search phase is thus likely to involve searching for different sorts of data, or studies from different domains, with which to test different aspects of any provisional theory.

Search methods using forward and backward citation tracking may be particularly valuable in finding the documents necessary to develop and then test provisional theories. Realist syntheses do not exclude sources solely on the basis of their study design; hence, 'methodological filters' (for example, to identify randomized controlled trials) may add little to the search and could potentially miss relevant papers.

Searching is likely to be iterative because, as the synthesis progresses, new or refined elements of theory may be required to explain particular findings, or to examine specific aspects of particular processes. As new elements of theory are included, searches for evidence to support, refute or refine those elements may be required. If undertaken, the process used for any such additional searches should be clearly documented. A single pre-defined search is unlikely to be sufficient and may suggest insufficient reflection on emerging findings.

Sufficient detail should be given to enable the reader to judge whether searching was likely to have located sources needed for theory building and/or testing.

***Item 9: Selection and appraisal of documents***

Explain how judgements were made about including and excluding data from documents, and justify these.

**Example**

"Three tools were developed (for identification, selection, and appraisal) in March, June, and October 2009, respectively. Modifications were made during each stage after piloting. Each stage processed a different type of data: citations in identification; full-text papers in selection; and sets of publications in appraisal.

...The identification tool consisted of three questions. This step funnelled the number of citations from 7,167 to 594.

The librarian (JH) retrieved the 594 full-text papers, which were read by two independent reviewers, using a selection tool initially comprised of six questions in June 2009, with an additional two questions added in October 2009. ...

Two hundred articles remained from 594 after filtering them through the selection tool. Due to the complexity of the dataset, we decided at this stage to further limit the scope of our review to community-based settings, and to participatory interventions. Our rationale was that: PR in all forms (community-based PR, organizational PR, action research) was too diverse to be assessed within one review; the complexity of PR benefits from community-based research provided a manageable set of studies; intervention research demonstrated more complexity of outcomes than non-intervention research, and would be best suited for analysis using realist review methods; and the pool of studies needed to be reduced to a manageable size for an in depth realist synthesis (analysis). Adding two questions reduced the pool to 83 studies.....

Contact with principal investigators of all full-text papers retained after selection was undertaken because descriptions of programs, methods and findings of PR interventions were found to be commonly described across a number of publications pertaining to the same intervention. It was thus necessary to confirm that we had complete sets of papers in order to fairly appraise projects according to the realist review approach. ... For each study, we then sent our list of papers to the corresponding author or PI, and asked them to confirm that we had the complete set, or to send us additional documents. ... Only those sets of studies in which the contacted researcher responded to our request were retained for appraisal.

.... The appraisal tool consisted of three questions. An additional 11 sets were eliminated after screening with the tool below, which left a total of 23 sets, comprising 276 documents that were retained for synthesis. See Appendix 4: ... for a complete breakdown of the number of cases retained at each stage." [30]

**Explanation**

Realist synthesis is not a technical process - that is, following a set protocol will not guarantee that a review will be robust. Rather, it requires a series of judgements about the relevance and robustness of particular data for the purposes of answering a specific question.

Within any document, there may be several pieces of data that serve different purposes, such as helping to build one theory, refining another theory and so on. Therefore, the selection (for inclusion or exclusion) and appraisal of the contribution of pieces of data within a document cannot be based on an overall assessment of study or

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document quality. An appraisal of the contribution of any section of data (within a document) should be made on two criteria:

- *Relevance* - whether it can contribute to theory building and/or testing; and
- *Rigor* - whether the method used to generate that particular piece of data is credible and trustworthy.

A wide range of documents can potentially contribute to a realist synthesis. For example, outcome and impact studies, qualitative interviews, ethnography, questionnaire surveys, mixed-method case studies, and close reading of policies, business plans, websites, project initiation documents and 'gray literature' write-ups of programs may all contribute in different ways of identifying and elucidating program theories. Because of this range and realist review's focus on relevance and rigor, it can initially be difficult to 'whittle down' the number of documents that are potentially eligible for inclusion in a review. This process can only occur as the data sources are analyzed in detail. Thus, in practice, the selection and appraisal stage may need to run in parallel with the analysis stage.

It is unlikely that authors will be able to provide an in-depth description of each decision involved, but the broad processes used to determine relevance and assess rigor (for example, using quality standards appropriate to particular kinds of research to appraise documents or sections of documents; discussion and/or debate within a review team of a document's findings; or consulting experts about technical aspects of methods or findings) should be described. While the description of the processes followed will not allow the reader to draw firm conclusions about judgements made, it will give an indication of the coherence, plausibility and appropriateness of the processes used to inform those judgements.

***Item 10: Data extraction***

Describe and explain which data or information were extracted from the included documents and justify this selection.

**Example**

"In order to identify key elements of importance to the success or failure of an intervention in a certain context using a realist perspective, information was gathered on the intervention, the context and the actual "working of the intervention" or the mechanisms. As we intended to discuss the strength of the evidence and the usefulness of the application of realist principles to already published studies, we developed a process of data analysis that was comprehensive and as objective and transparent as possible. Therefore, a data analysis matrix was developed by the team of authors (see Annex 2). During the development of this matrix, the team extensively discussed and defined terms (such as context, mechanisms and outcome) and evaluation levels (such as process, output and outcome)." [31]

**Explanation**

In a realist synthesis, data extraction assists analysis and synthesis. Reporting on what was extracted and why can add to the transparency of the synthesis process.

The extracted data may consist of descriptions (for example, of the detail of what was done in a program), findings (for example, cure rates, mortality) or explanations about how and why the program may have worked in particular contexts. Of particular interest to the realist reviewer are data that support the use of realist logic to answer the review's question(s) - for example, data on context, mechanisms and outcome configurations, demi-regularities, middle-range and/or program theories. Realist synthesis is used for a wide range of research questions, so it is impossible to be prescriptive about what data should be extracted. However, the link between the research question and the category of data extracted should be clear.

***Item 11: Analysis and synthesis processes***

Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.

**Example**

"Data synthesis was undertaken either by RP and/or GW and synthesis results were regularly shared and discussed within the review team to ensure validity and consistency in the inferences made. Specifically (where relevant), we attempted to identify prominent recurrent patterns of contexts and outcomes (demi-regularities) in the data and then sought to explain these through the means (mechanisms) by which they occurred. For example, we noted that in our included articles self-reported public support for a ban on smoking in vehicles carrying children was often found to be high amongst smokers. During data synthesis we would then aim to provide an explanation of this demi-regularity through the identification of mechanism(s). As we delved further into our included articles and beyond (through our aforementioned purposive searching) for an explanation, data emerged that smokers harboured within them the wish to want to protect children from harm and also regret at having started smoking. We interpreted these as (realist) mechanisms and, for the former, were able to find substantive (middle-range) theory in the form of the Millean principle [Reference x1] to explain its interaction with context to influence outcomes. When additional studies were sought to enable programme theory testing, data handling processes .... were repeated." [26]

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**Explanation**

In a realist synthesis, the analysis and synthesis processes occur iteratively and may be sequential or in parallel. At the center of any realist analysis is the application of a realist philosophical 'lens' to data. A realist analysis of data specifically seeks to analyze data using realist concepts. Specifically, realism adheres to a generative explanation for causation - that is, an outcome (O) of interest was generated by relevant mechanism(s) (M) being triggered in context (C). Within or across the included documents, recurrent patterns of outcomes (or demi-regularities) and their associated mechanisms and contexts (CMO configurations) are likely to occur.

During synthesis the goal is to make sense of the analyzed data using theory, at one of two levels. First, theory (or theories) may be sought, developed and/or refined to explain how it is that a program (or part of a program) achieves its outcomes (that is, the mechanism(s) operating within a program) and the contexts in which those mechanisms do and do not fire. This provides a realist program theory. Second, theory (or theories) may be sought, developed and/or refined to explain, at a somewhat more general level, the pattern of contexts, mechanisms and outcomes. A full realist analysis addresses both these levels and attempts to make sense of the relationship between these two levels. Syntheses which address only one level may also be considered realist syntheses assuming that they apply and demonstrate application of a realist philosophy of science. The level(s) of analysis chosen will depend on the review's focus. The theories used may have been developed and/or refined from the data and/or be refinement of existing substantive theory.

The key analytic process in realist review involves iterative testing and refinement of theoretically based explanations using empirical findings in data sources. Reviewers may draw on any appropriate analytic techniques to undertake this testing. Explanation and justification for the choice of techniques should be provided.

Ideally a description should be provided on how all the individuals involved in the review have been involved in the analysis and synthesis processes, and how these evolved as the review took shape.

**Results section**

The following items should be reported in the results section.

***Item 12: Document flow diagram***

Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example provided (which is likely to need modification to suit the data) in Figure 1.

**Example**

"See Figure 1: Flow diagram illustrating search process and article disposition." [26]

**Explanation**

A flow diagram provides an accessible summary of the sequence of steps and gives an indication of the volume of data included and excluded at each step.

***Item 13: Document characteristics***

Provide information on the characteristics of the documents included in the synthesis.

**Example**

"Additional File 1 summarises ..., the context, the intervention, the mechanisms triggered and the reported outcomes. Additional File 1 shows that in all the trials, more than one type of intervention was applied to improve CHWs [community health workers] performance. It also shows that the outcomes are reported not in terms of CHW performance, but rather in terms of the consequences of their performance on specific health outcomes." [27]

**Explanation**

A clear summary of the characteristics of included sources can add to the transparency of the synthesis and some characteristics may help readers judge the coherence and plausibility of inferences. Examples of possibly relevant characteristics of documents that may be worth reporting include, where applicable: full citation, country of origin, study design, summary of key main findings, use made of document in the synthesis and relationship of documents to each other (for example, there may be more than one document reporting on an intervention). While considering specific requirements of any particular publication, reviewers may wish to tabulate key characteristics.

***Item 14: Main findings***

Present the key findings with a specific focus on theory building and testing.

**Example**

"Using this theoretical concept, we hypothesized that equitable partnerships, with the stakeholders' participation throughout the project, succeed largely through synergy. Through the synthesis process using CMO configuring, we refined the theory by demonstrating that synergy is both an outcome and a context for partnership development - so that when synergy generated positive outcomes (e.g., enhanced trust or improved data collection), those outcomes generated new synergy. Expanding this logic, we demonstrated how partnership synergy created momentum over time, producing resilience in the face of obstacles as well as sustaining health-related goals, extending

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programs and infrastructure, and creating new and unexpected ideas and activities." [30]

**Explanation**

The defining feature of a realist synthesis is the nature of the theory(ies) it offers. Such a theory explains why a social program/intervention generates particular outcomes in particular contexts, in terms of one or more mechanisms - that is how the program's infrastructure and resources trigger particular decisions or behaviors in human participants. Program theories are usually 'middle-range' - that is, specific enough to generate propositions that can be tested about aspects of the program but sufficiently abstract to be applicable to other programs. Mechanisms are contingent: they are causal processes that have a tendency to occur in a particular set of conditions, but which do not always occur (because the circumstances have to be right for any particular mechanism to operate, and because many mechanisms can operate concurrently, sometimes cancelling each other out).

The validity of a review which is described as 'realist' and which talks about program theories or mechanisms but which expresses these as simple and linear relationships between variables should be questioned.

The findings of a realist synthesis consist largely of inferences about the links between context, mechanism and outcome and the theory(ies) that seek to account for these links. It is important that where inferences are made these are clearly articulated. Where possible, especially for key findings, it is important to include an explanation to show how these inferences were arrived at.

Transparency of the synthesis process can be demonstrated, for example, by including such things as a detailed worked example, verbatim quotes from primary sources, and (if appropriate) an exploration of disconfirming data (that is, findings which appeared to refute the program theory but which, on closer analysis, could be explained by other contextual influences).

When presenting inferences about context-mechanism-outcome configurations, reviewers should be clear about what they have categorized as context, what as mechanism and what as outcome. In a realist synthesis a mechanism involves the interaction between particular inputs (or resources) and human reasoning, which produces a particular outcome (or not).

More than one piece of data might be needed to support an inference. It is sometimes appropriate to build the argument for an inference as an unfolding narrative in which successive data sources increase the strength of the inference [32]. Provide enough details about each data item to identify its source and enable readers to make judgements about its relevance and rigor.

**Discussion section**

The following Items should be reported in the discussion section.

***Item 15: Summary of findings***

Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s).

**Example**

"This realist review of 249 primary studies has produced two key findings which are important, if somewhat unsurprising. First, Internet-based courses must engage their target group of learners to use the technology. This is likely to occur only if the technology is perceived as 'useful' (e.g.increases access to learning or saves time) and 'easy to use', though benefits in the former can outweigh challenges in the latter. Second, 'interactivity' is highly valued by learners. Learners wanted to be able to enter into a dialogue with the course tutor, fellow students and/or a virtual tutorial and obtain ongoing feedback on their understanding and performance." [29]

**Explanation**

In order to place the findings in the context of the wider literature and any specific policy need, it is necessary to summarize briefly what has been found. This section should be succinct and balanced, explaining the relevance of one or more key theories that emerged from the analysis and highlighting the strength of evidence for the main inferences. This should be done with careful attention to the needs of the main users of the synthesis.

***Item 16: Strengths, limitations and future research directions***

Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged.

The limitations identified may point to areas where further work is needed.

**Example**

"We explicitly chose to do a realist review of the RCTs [randomized controlled trials] to see what they could additionally yield. While the CHWs [community health workers] were an important component of the interventions being tested in the RCTs, none of the RCTs under review explicitly focused on performance of the CHW as an outcome. The RCTs under review offered a fair amount of information about the interventions, only some information about context - allowing us to formulate only generic hypotheses. ...

... Authors seldom described or discussed the mechanisms that explained their study outcomes. We realise that

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the RCT design, the exacting reporting requirements and word limits of journals, restrict authors from sharing all their operational experiences. In addition RCTs tend to report average effects and not differential effects of interventions, and less so of the context and rarely of the mechanisms triggered by their interactions. This makes the RCTs less useful for answering the questions regarding how interventions work. These generic hypotheses seem to be recurring in the literature, however they have not been explicitly tested across contexts." [27]

**Explanation**

Realist synthesis may be constrained by time and resources, by the skill mix and collective experience of the research team, by the scope of the review's questions or objectives and/or by anticipated or unanticipated challenges in the data. These should be made explicit so that readers can interpret the findings in the light of them. A common challenge in realist synthesis is that in order to focus the synthesis, some material is omitted at each successive stage. Some aspects of the topic area, therefore, end up being reviewed in detail and rich explanatory insights produced for these. Other aspects are neglected (relatively or absolutely). It is thus inevitable that in generating illumination, the synthesis will also cast shadows. These should be highlighted in the discussion so as to indicate areas where other syntheses might focus.

Strengths and/or limitations associated with any modifications made to the synthesis process should also be reported and justified.

***Item 17: Comparison with existing literature***

Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic.

**Example**

"We were unable to find any comparable attempt at providing an evidence-based-policy framework such as ours. However, we acknowledge that some sections of our framework may be found in sources we have not uncovered and also as tacit knowledge within the heads of seasoned practitioners (e.g. advocates or legislators). We do however hope that our attempts to develop and test it on our one 'case study' will make a primordial tool that will be useful to policy and decisions makers less well versed in the arena of public health legislation." [26]

**Explanation**

Comparing and contrasting the findings from a synthesis with the existing literature may help readers to put these into context. For example, this item might cover questions such as: How does this synthesis compare to other reviews (for example, were they theory-driven?); What does this synthesis add?; Which body of work in particular does it add to?; Has this synthesis reached the same or different conclusion to previous reviews?; and Has it answered a question previously identified as important in the field?

***Item 18: Conclusion and recommendations***

List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.

**Example**

"Our realist review was based on a housing intervention in the United States, but the results can potentially be applied to urban centers in other nations that implement housing interventions that involve moving families. When a family moves, the experience is likely to be different for each member of the household, and differences in mental health outcomes of moving may occur (Reference x1). All communities, rich or poor, and irrespective of geographic location, should be viewed as complex systems, and as composed of people with social relationships that influence the functioning and health of community members." [28]

**Explanation**

A clear line of reasoning is needed to link the findings (Results section) with the implications (Discussion and/or Conclusion). If the synthesis is small and preliminary, or if the coherence and plausibility of evidence behind the inferences is weak or moderate, statements about implications for practice and policy should be appropriately guarded.

If recommendations are given, these should take into account the focus of the synthesis and needs of the intended audience and be presented appropriately. The explanations in realist analysis are highly dependent on contextual influences. It follows that recommendations must be contingent (for example, only under certain contexts will a particular mechanism be triggered to generate the desired outcome) rather than statements that X should or should not be done.

***Item 19: Funding***

Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers.

**Example**

"We gratefully acknowledge a financial contribution from the Dutch Development Cooperation (DGIS)." [25]

**Explanation**

The source of funding for a synthesis and/or personal conflicts of interests may influence the research question, methods, data analysis and conclusions. No review is a 'view from nowhere', and readers will be better able to interpret the review if they know why it was done and for which sponsor.

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If a synthesis is published, the process for reporting funding and conflicts of interest as set out by the publication concerned should be followed.

## Discussion

We have developed these publication standards for realist synthesis (which we view as synonymous with realist review) by drawing together a range of sources - namely, existing published evidence, a Delphi panel and comment, discussion and feedback from a mailing list, training sessions and workshops. We hope these standards will lead to greater consistency and rigor of reporting and, thereby, make the outputs of realist synthesis more accessible, usable and helpful to different stakeholders.

This publication standard is not a detailed guide of how to undertake a realist synthesis. Other resources, both published (see Background) and in preparation, are better suited for this purpose. These standards have been developed as a guide to assist the quality of reporting of realist syntheses and the work of publishers, editors and reviewers. As part of the RAMESES project, we will be developing and disseminating both training materials and quality standards for realist synthesis [20].

Because realist synthesis is used for a broad range of topics and questions, and because it involves making judgements and inferences rather then checking against or following a technical checklist, it is impossible to be prescriptive about what exactly must be done in a review. The guiding principle is that transparency is important, as this will help readers to decide for themselves if the arguments for the judgements made were reasonable, both for the chosen topic and from a methodological perspective. We strongly encourage review authors to provide detail on what they have done and how - in particular with respect to the analytic processes used. These standards are intended to supplement rather than replace the exercise of judgement by editors, reviewers, readers and users of realist syntheses. We have tried to indicate in each item where judgement needs to be exercised.

The explanatory and theory-driven focus of realist syntheses means that detailed data may need to be reported in order to provide enough support for inferences and/or judgments made. While developing these publication standards, it became apparent that in some cases the word count limitations imposed by journals did not enable review teams to fully explain aspects of their synthesis - such as how judgments were made or inferences arrived at. Alternative ways of providing the necessary detail may need to be found, such as online appendices or additional files available from authors on request.

Previous efforts to develop publication standards have sometimes been criticized for being too 'ivory-tower' and failing to take account of real-world problems faced by reviewers. In an effort to redress this problem in the RAMESES project, we sought from the outset to engage not just senior academics but also junior and mid-career researchers, practitioners, policymakers and publishers in the development of the standards and to capture real-life challenges of ongoing realist syntheses as these emerged.

## Conclusions

We have developed these publication standards for realist syntheses by drawing on a range of sources. Our hope is that these standards will lead to greater consistency and rigor of reporting and make the outputs of realist syntheses more accessible, usable and helpful to different stakeholders. Realist synthesis is a relatively new approach to evidence synthesis and with increasing use and methodological development, changes are likely to be needed to any publication standards. We hope to continue capturing and improving these publication standards, through our email list [21] and wider links and discussions with researchers and those who commission, sponsor, publish and use realist syntheses.

### Abbreviations

ESRC: Economic and Social Research Council; RAMESES: Realist And MEta-narrative Evidence Syntheses: Evolving Standards).

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**Authors' contributions**

GWo carried out the literature review. JB searched the literature for realist syntheses. GWo, TG, GWe and RP analyzed the findings from the review and produced the materials for the Delphi panel. They also analyzed the results of the Delphi panel. GWo, TG, GWe and RP conceived of the study and participated in its design. GWo coordinated the study and ran the Delphi panel. All authors read and approved the final manuscript.

**Competing interests**

The authors declare that they have no competing interests. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR program, NIHR, NHS or the Department of Health.

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**References**

1. Pawson R: *Evidence-based Policy: A Realist Perspective* London: Sage; 2006.
2. Pearson M, Coomber R: **The challenge of external validity in policy-relevant systematic reviews: a case study from the field of substance misuse.** *Addiction* 2010, **105**:136-145.
3. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A: **Synthesising qualitative and quantitative evidence: a review of possible methods.** *J Health Serv Res Policy* 2005, **10**:45-53.
4. Barnett-Page E, Thomas J: **Methods for the synthesis of qualitative research: a critical review.** *BMC Med Res Methodol* 2009, **9**:59.
5. Pope P, Mays N, Popay J: *Synthesizing Qualitative and Quantitative Health Research: A Guide to Methods* Maidenhead, UK: Open University Press; 2007.
6. Gough D, Oliver S, Thomas J: *An Introduction to Systematic Reviews* London: Sage; 2012.
7. Kastner M, Tricco A, Soobiah C, Lillie E, Perrier L, Horsley T, Welch V, Cogo E, Antony J, Straus S: **What is the most appropriate knowledge synthesis method to conduct a review? Protocol for a scoping review.** *BMC Med Res Methodol* 2012, **12**:114.
8. Merton R: *On Theoretical Sociology. Five Essays, Old and New* New York: The Free Press; 1967.
9. Astbury B, Leeuw FL: **Unpacking black boxes: mechanisms and theory building in evaluation.** *Am J Eval* 2010, **31**:363-381.
10. Shepperd S, Lewin L, Straus S, Clarke M, Eccles M, Fitzpatrick R, Wong G, Sheikh A: **Can we systematically review studies that evaluate complex interventions?** *PLoS Med* 2009, **6**:e1000086.
11. Rycroft-Malone J, McCormack B, Hutchinson AM, DeCorby K, Bucknall TK, Kent B, Schultz A, Snelgrove-Clarke E, Stetler CB, Titler M, Wallin L, Wilson V: **Realist synthesis: illustrating the method for implementation research.** *Implement Sci* 2012, **7**:33.
12. Robert E, Ridde V, Marchal B, Fournier P: **Protocol: a realist review of user fee exemption policies for health services in Africa.** *BMJ Open* 2012, **2**: e000706.
13. Pawson R: **Evidence-based policy: the promise of 'realist synthesis'.** *Evaluation* 2002, **8**:340-358.
14. Pawson R, Greenhalgh T, Harvey G, Walshe K: *Realist Synthesis - an Introduction. ESRC Working Paper Series* London: Economic and Social Research Council; 2004.
15. Pawson R, Greenhalgh T, Harvey G, Walshe K: **Realist review–a new method of systematic review designed for complex policy interventions.** *J Health Serv Res Policy* 2005, **10(Suppl 1)**:21-34.
16. Moher D, Hopewell S, Schulz K, Montori V, Gotzsche P, Devereaux P, Elbourne D, Egger M, Altman D, for the CONSORT Group: **CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trial.** *BMJ* 2010, **340**:c869.
17. Brouwers M, Kho M, Browman G, Burgers J, Cluzeau F, Feder G, Fervers B, Graham I, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L, AGREE Next Steps Consortium: **AGREE II: advancing guideline development, reporting and evaluation in healthcare.** *Can Med Assoc J* 2010, **182**:E839-842.
18. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D: **The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration.** *BMJ* 2009, **339**: b2700.
19. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S, SQUIRE Development Group: **Publication guidelines for improvement studies in health care: evolution of the SQUIRE project.** *Ann Intern Med* 2008, **149**:670-676.
20. Greenhalgh T, Wong G, Westhorp G, Pawson R: **Protocol - realist and meta-narrative evidence synthesis: evolving standards (RAMESES).** *BMC Med Res Methodol* 2011, **11**:115.
21. RAMESES JISCM@il: [www.jiscmail.ac.uk/RAMESES].
22. Wong G, Greenhalgh T, Westhorp G, Pawson R: **Realist methods in medical education research: what are they and what can they contribute?** *Med Educ* 2012, **46**:89-96.
23. Wong G: **The internet in medical education: a worked example of a realist review.** In *Synthesising Qualitative Research: Choosing the Right Approach.* Edited by: Hannes K, Lockwood C. Chicester, UK: Wiley-Blackwell; 2011:.
24. EQUATOR Network: [http://www.equator-network.org/home/].
25. Dieleman M, Gerretsen B, van der Wilt GJ: **Human resource management interventions to improve health workers' performance in low and middle income countries: a realist review.** *Health Res Policy Syst* 2009, **7**:7.
26. Wong G, Pawson R, Owen L: **Policy guidance on threats to legislative interventions in public health: a realist synthesis.** *BMC Public Health* 2011, **11**:222.
27. Kane SS, Gerretsen B, Scherpbier R, Dal Poz M, Dieleman M: **A realist synthesis of randomised control trials involving use of community health workers for delivering child health interventions in low and middle income countries.** *BMC Health Serv Res* 2010, **10**:286.
28. Jackson L, Langille L, Lyons R, Hughes J, Martin D, Winstanley V: **Does moving from a high-poverty to lower-poverty neighborhood improve mental health? A realist review of 'Moving to Opportunity'.** *Health Place* 2009, **15**:961-970.
29. Wong G, Greenhalgh T, Pawson R: **Internet-based medical education: a realist review of what works, for whom and in what circumstances.** *BMC Med Educ* 2010, **10**:12.
30. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, Sirett E, Wong G, Cargo M, Herbert CP, Seifer SD, Green LW, Greenhalgh T: **Uncovering the benefits of participatory research: implications of a realist review for health research and practice.** *Milbank Q* 2012, **90**:311-346.
31. Dieleman M, Kane S, Zwanikken P, Gerretsen B: *Realist Review and Synthesis of Retention Studies for Health Workers in Rural and Remote Areas* Geneva, Switzerland: World Health Organization; 2011.
32. Pawson R, Wong G, Owen L: **Known knowns, known unknowns, unknown unknowns: the predicament of evidence-based policy.** *Am J Eval* 2011.

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**Supplementary file 2: RAMESES publication standards checklist**

| | | |
|---|---|---|
| 1 | Title identified as realist review | Yes |
| 2 | Abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice. | Yes |
| 3 | Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area. | yes |
| 4 | State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review. | yes |
| 5 | Any changes made to the review that was initially planned should be briefly described and justified. | Yes |
| 6 | Explain why realist synthesis was considered the most appropriate method to use. | Yes |
| 7 | Describe and justify the initial process of exploratory scoping of the literature. | Yes |
| 8 | state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected. | Yes |
| 9 | Explain how judgements were made about including and excluding data from documents, and justify these. | Yes |
| 10 | Describe and explain which data or information were extracted from the included documents and justify this selection. | Yes |
| 11 | Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process. | Yes |

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| 12 | Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). | Yes |
| 13 | Provide information on the characteristics of the documents included in the synthesis. | Yes |
| 14 | Present the key findings with a specific focus on theory building and testing. | Yes, although theory testing was limited due to limited evidence, this is discussed in the paper |
| 15 | Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s). | Yes |
| 16 | Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged. The limitations identified may point to areas where further work is needed. | Yes |
| 17 | Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic. | Yes |
| 18 | List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice. | Yes |
| 19 | Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers. | Yes |

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Supplementary file 3: Data extraction form

# Theory Areas

1. **If a change agent supports staff to understand how to interpret and respond to PLWD behaviour that uses PCC approaches, challenges poor practice by using experiential learning and patient centred resources and reflection, then staff will be more likely (mechanism confidence, awareness, prioritise) to engage and assess patient pain / distress and involve PLWD and carer in planning their care**

2. **If a change agent has organisational and clinical authority to introduce learning and credible resources that prioritise the identification and care of PLWD and addresses concerns around risk and workplace disruption within a PCC framework then staff will feel they have permission to do the right thing becoming less risk averse**

3. **If a change agent works as a clinical expert to identify and resolve the care needs of PLWD then staff will feel supported and be more willing to care for PLWD**

| ***Source**(ref):* | |
|---|---|
| **Author lens** | |
| **Country** | |
| **Type of study/paper** | |
| **Intervention** | |
| **Relevance:**<br>*Are the contents of a section of text within an included document referring to data that might be relevant to our mid-range theories? Which ones?* | |
| | |
| 2. Outcomes of interest<br>Are the outcomes of interest referred to in the paper? Which ones? | |
| 1) Patient and carer involvement in decision making<br>2) Length of hospital admission<br>3) Occurrence of adverse incidents (falls, nutrition, delirium)<br>4) Use of antipsychotic medication<br>5) Needs assessment<br>6) Patient and carer satisfaction<br>7) Other not specified | |
| **What are the characteristics of the change agent** | |
| | |
| **What are the characteristics of person centred care** | |
| | |
| **What is the change agent trying to do** | |
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| **What resources are in place to help them achieve their aims** |
| |
| **To what extent are their aims achieved, what is the evidence?** |
| |
| **In what context is the change agent working?** |
| |
| **3. Interpretation of meaning:**<br>*If it is relevant, do the contents of a section of text provide data that may be interpreted as being context, mechanism (resource/response) or outcome?* |
| |
| **4. Judgements about Context-Mechanism-Outcome-Configurations:**<br>*What is the Mechanism (resource)-Context-Mechanism (response)-Outcome Configuration (CMOC) (partial or complete) for the data?* |

| Resource/Intervention | Context | Mechanism | Outcome |
|---|---|---|---|
| | | | |

| |
|---|
| **5. Judgements about mid-range theory:**<br>• *How does this (full or partial) CMOC relate to the mid-range theory?*<br>• *Within this same document are there data which informs how the CMOC relates to the mid-range theory?*<br>• *If not, are these data in other documents? Which ones?*<br>• *In light of this CMOC and any supporting data, does the mid-range theory need to be changed?* |
| |
| **6. Rigour:**<br>• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the CMOC?*<br>• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the mid-range theory?* |
| |
| **7. Population** |
| |
| **Questions raised not captured elsewhere** |
| |
| **Notes** |
| |

Supplementary file 2

Evidence for theory area 1: To support staff awareness and learning

| Paper | Example Evidence | Key Points and emerging CMOs |
|---|---|---|
| Baillie (2015) [59] | "I think the Barbara's Story made me more aware of them so I go to help them where perhaps I may not necessarily have noticed them before. (Therapists1)" (p26)<br><br>"After seeing the video it makes those kinds of patients easier to speak with and it also reassures you, so for example in the video it talks about not taking them out of their own reality, and I think that just reassures people that you can distract them and not 'lie' to them and that's okay, and I think that's reassuring to people that don't know that much about dementia." (p46)<br><br>"Staff remembered Barbara being 'lost', 'confused', 'vulnerable', 'scared' and 'worried'. They engaged with her as a person who could be a family member… Some staff specifically related Barbara's Story to a family member, which personalised the film's story… There was also acknowledgement that any of us could find ourselves in a similar situation." (p24)<br><br>"Barbara's Story enabled staff to see her healthcare experience from her perspective and the behaviour shown in the film prompted staff to reflect on their own behaviour and that of colleagues." (p23)<br><br>"In most focus groups, staff discussed how their own interactions with patients and behaviour had changed since watching Barbara's Story, and they often referred to changes they had observed in other staff too. Areas discussed included: giving more time to patients, improved communication, giving more information, and assisting patients who are looking lost." (p25) | Raising awareness to recognise signs and symptoms of dementia<br><br>Training to improve confidence in working with people living with dementia<br><br>Reassurance from examples in training of how to work well with people living with dementia<br><br>Training that developed empathy helped staff relate to people living with dementia as family members<br><br>Shown experience from patient's viewpoint to understand how need to adapt care practices<br><br>Changes staff implemented after training; time for patients, better communication, information, recognising and acting upon distress and confusion. |

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| | Some participants considered that Barbara's Story had raised the profile of initiatives and other work that was already in place for people with dementia, further reinforcing and helping developments to embed in the Trust, such as dementia study days and dementia champions and use of the forget-me-not." (p29) | Training supporting and promoting the use of other resources. |
| | "Staff related how they listened to patients with a history of dementia, taking their physical symptoms more seriously, rather than attributing them to their dementia: 'we will now investigate it a little bit more [...] any physical symptoms we will take seriously' [rather than attributing it to their dementia or mental health condition (Nurse10). Similarly, in relation to behaviour, another nurse said:<br>I think it's really important for staff to remember not to play a part in that stigma and not to make excuses if they're upset or aggressive, not to put it down to their condition, sometimes they are just genuinely wanting something or upset. (Nurses8)" (p51) | Staff reported changes to practices following training. Understanding behaviours as communication of other needs rather than symptoms of dementia. |
| | "Those who had used This is me were great advocates for the tool and the difference it made in practice:<br>I saw it once in practice and I thought to myself, this is the best thing that anyone has ever done because it just made the care you gave so personalised and I remember the patient and it said in the notes, loves Coronation Street and EastEnders. So at 7.30pm I'd go and put on Coronation Street, just because I knew about it. (Nurses4)<br>… It's nice to know a bit more about them, what they like and don't like, even if it's just down to how they like their tea or they don't like tea. (Nurses6)" p53 | Use of biographical tool to understand the preferences and routines of the patient. |
| | In one focus group, an example of the benefits of This is me was explained:<br>She [patient with dementia] was in for less than three days, got home, she wasn't a delayed discharge but my point had been if This Is me hadn't been filled in and she was distressed and constantly calling, they'd have given her [medication], shut her up, then she'd have been over-sedated, she wouldn't have been eating and drinking, her delirium would have been worse. (Nurses4) | How not knowing about the patient leads to distressed behaviours that might have adverse results such as inappropriate medication, poor nutrition and hydration, and increased severity of delirium. |

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| Banks (2014) [40] | "[this is me] By having this document we have reduced the amount of medication the patient receives in hospital. Staff are much more likely to look into why the patient is behaving this way rather than get them prescribed medication. This in turn has reduced the number of falls during the day, therefore reducing the number of fractures and increased stays in hospital. P727<br><br>The first change we made was to stop separating the patient with dementia from the relative during the admission process. ... I think the relatives feel more valued as a carer and the importance of their role in looking after their relative with dementia is recognised. The patients are also much more relaxed to have familiar faces around so the admission process has become much smoother for everyone including the staff p727<br><br>I have tried to take back to the ward with me topics that I have learned and shared with other members of staff. This has been an eye opener as some staff are not keen to accept change and question everything that I have tried to do and don't seem to see the need for change. P728 | Resources that support knowledge of the patient reduce adverse events such as inappropriate medication, falls, and increased length of stay. Resources that support knowledge of the patient encourage staff to understand behaviour as a form of communication.<br><br>Changing processes and procedures that understand the needs of people living with dementia to reduce patient distress and improve carer satisfaction.<br><br>Difficulty in getting staff to change practices if they do not recognise the need to change practices. |
| Brooker (2014) [63] | "[Dementia awareness training] It has made a big difference to how staff respond to the behaviour of patients with dementia, as it has increased understanding and awareness. For example, there is now a greater focus on occupying patients with activities to reduce behaviour that challenges, and staff are now seen to be walking around with patients with dementia who are wandering when previously they would have told them to sit back down." P48 | Dementia awareness training improves staff understanding of how to better support people living with dementia. Understand the need for providing activities to reduce onset of behaviours that challenge and adapting way of working. |
| Dowding (2016) [60] | Participants discussed how pain may be intermittent and fluctuate, often only being present when patients are engaged in certain activities. ''often the doctors will go round and they'll ask the patient in their bed or in their chair, ''Oh, are you alright? Any pain anywhere?'', ''No, I'm fine''. As soon as we [physiotherapists] come, get them up on it, ''Oh, oh, that really hurts''.[H1, physiotherapist] p156 | Need to understand people living with dementia have difficulty communicating their needs (e.g. pain relief) and will have problems recalling and describing experiences of pain. |

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| | As with other patients, one of the challenges faced by clinicians is the initial recognition of whether or not a patient may be in pain at all; for a variety of reasons patients (including those with cognitive impairment) may not be able to verbally express they have pain, and clinicians often find it challenging to interpret behavioural signals which may be 'atypical' in nature. p157<br><br>One of the key factors in assessing and managing pain is the ability to build a 'picture' or narrative of the patient case; which is used as the basis for the interpretation of cues, to try and 'make sense' of a situation. Participants highlighted the importance of building patterns of information cues and patient behaviour, to help inform their decision making. This narrative occurred over time (an issue which arose in other themes from the data), trying to link different events over the trajectory of a patient stay, to help test 'guesses' and form the basis of trial and error approaches to management. P157<br><br>From the observations it appeared that pain recognition, assessment and management was carried out over time, by many individuals. Rather than being under the control of one specific nurse or other health care professional, it could be characterized more as a process of distributed work, which is time dependent. This is reflected in the comments in interviews, which highlight how there is a division of labour in the hospital ward; there numerous people with different professional roles who are all involved in the care of each patient, each with specific duties, responsibilities and powers. In turn, these roles often governed which part of the pain recognition, assessment and management process they participated in, and how they communicated their findings. p158 | Challenges for staff to understand patient needs.<br><br>Getting to know the needs of the patient through time and continuity in their care.<br><br>Context of ward where responsibilities for the patient's needs are across a number of staff; those who recognise the need may not be able to directly address the need. Importance of communication with colleagues. |
| Duffin (2013) [64] | 'Some people have been moved to tears by the DVDs,'(outcome) says Ms Karasu. 'The films resonate with them. Sometimes you see a look on their face and you can tell they are thinking: "I never thought of that." (reasoning) P16 | Emotional engagement with training and realisation of the patient's experiences of care. |

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| | In one training session nurses, doctors and other staff wear specially designed goggles that restrict their vision, and put on a jacket which has small splints inserted in the arms to restrict movement of their upper body. This is to help staff understand the physical constraints faced by some older people. Darlene Romero, a matron across the trust's three older people's wards, who delivers the training, says: 'It's a real eye opener, and makes you realise how difficult it can be to go to the toilet. P16<br><br>A laminated symbol of a forget-me-not is placed above the beds of all patients with dementia, and a similar motif is put on their casenotes, so that any health worker who comes into contact with them is aware of their condition. Ms Wood says: 'It shows our team that they need to adapt because the person with them has a cognitive impairment. If someone goes to have an X-ray, for example, the team would see the forget-me-not symbol and they would know that this person may not just jump up onto the couch and be ready. They will need to provide more explanation and perhaps to stay a bit calmer than they would with other patients to show extra sensitivity. P17 | Experiential learning triggering realisation of patient needs.<br><br>Identifying a patient has dementia, staff recognising they need to adapt care to be appropriate to the needs of the patient. |
| Edvardsson (2012) [65] | The subtle initial expression of emerging needs were not picked up by staff as they were absent and the expression of unmet needs could escalate to become behavioural alterations as the need remained unsatisfied. When staff finally came about, they were observed to interpret the behaviour as 'disruptive' or 'disturbing' as they lacked the initial interpretative cues that could explain the behaviour. As a consequence, care became very much reactive, as staff had to come up with acute solutions to full-blown situations for which they lacked the insight and an interpretative framework. P6 | Care becomes reactive when behaviour is misinterpreted. Underlying causes not investigated. |
| Ellison (2014) [42] | Colleagues reported improved skills, knowledge and understanding as well as improved confidence in caring for people with dementia as a result of the training and working alongside a Champion. Colleagues also reported changes in their practice as a result of training, for example:<br>spending more time with people with dementia on a one to one basis to provide more | Training supported by a Champion to improve knowledge and understanding of dementia and confidence to work well with people living with dementia. Staff reported changes to care practices. |

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| | individualised care; more effective communication as a result of a better understanding of the needs of people with dementia; involving carers more proactively; understanding the importance of personal care plans and documentation; being more aware of the impact of the environment on people with dementia; being more proactive in providing additional assistance to people with dementia; being prepared to challenge bed moves involving people with dementia when there was no clinical need; increased awareness of signs of stress and distress and seeking to identify the cause rather than resort to use of sedatives. p51 | Staff seeking to address underlying need of people living with dementia rather than treating behaviour with medication. |
| | The primary actions undertaken in this respect have been the implementation of person-centred care planning through use of the 'This is Me' document initially, and subsequent development and implementation of 'Getting to Know Me'. Many DCs have played a key role in implementing and trying to embed these documents through introducing it to their team and training staff in its application. … Use of GTKM allows staff to find out more about the patient and their preferences and is generally considered a useful tool in supporting improved person-centred care for people with dementia. Comments from Champions and their colleagues working in acute settings suggest that use of person-centred plans like this represents a departure from the norm for them in terms of the information they are used to collecting and the conversations they are used to having with patients. Examples were cited where staff have used GTKM more effectively minimise stress and distress, reporting how the information they gained about the patient through the assessment had supported them to recognise and respond more effectively to distressed behaviour. p53 | Use of biographical tools to support person centred care practices that reduce distress.<br>Role of champions in supporting implementation of tool. |
| | In interviews DCs frequently cited the role they have played in influencing the behaviour of colleagues, for example by challenging inappropriate use of language when speaking to or speaking about people with dementia. p54 | Champions role in addressing negative staff attitudes towards people living with dementia. |

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| | "Staff's attitudes have changed hugely in A&E [as a result of DC's awareness raising of how noise and activity can cause distress] – you used to see someone with dementia and there would be 2 or 3 nurses with the one patient, each doing something else and the poor patient... now you see them going in one person at a time, calmer more quietly."p56 | Champion supports staff to understand difficulties faced by people living with dementia. Staff adapt practices to recognise and support difficulties. |
| Galvin (2010) [10] | [post training] The staff also recognized the need for improved communication skills with the patient, such as sitting and talking clearly, using nonverbal clues, and asking permission to touch the patient in order to improve care. | Training for staff to recognise the need to change practices.<br><br>Additional evidence of how training encouraged staff to implement new resources to improve care of people living with dementia (activity packs, volunteers, identification method for patients at risk of leaving the ward). |
| Goldberg (2014) [50] | Staff also appeared more accepting and understanding of mental health problems and patients on the Unit were more likely to raise concerns about their mental health and these would be responded to by staff. This could be because staff were more aware of mental health needs, because they had more conversations with staff in general (and thus the opportunity to raise such concerns) or it could be because they were cared for on a ward where all patients were cognitively impaired. (p1337)<br><br>The Unit provided a greater focus on the mental health needs of patients. Staff were more often observed assessing patients' cognitive abilities (using standardised tools and by questioning) than on standard care. P1337<br><br>Sometimes, skilled care on the Unit was not evident to observers, as patients who had the potential to exhibited distress behaviour were calm. In this observation Alex has been calmly walking up and down the ward for over an hour. A member of staff has always been walking with him and talking to him. Alex's aggression was only evident when something unexpected happened. P1337 | Awareness and understanding of dementia led staff to address patient psychological and mental health needs.<br><br>Use of assessment tools to understand patients' cognitive abilities.<br><br>Supporting patient choice and independence to reduce distress and the onset of behaviours that challenge. |

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| | Individual attention was given to patients at other times on the Unit with staff getting patients drinks or snacks outside of the meal and drink rounds and using touch when interacting with patients. P1338<br><br>However, the psychological needs of the patients on the Unit were high and a minority of patients would call out persistently for long periods of time. Staff would try to comfort or distract them… But the calling out would resume once the staff member left the patient and the conflicting demands on time meant staff would sometimes ignore their cries and attend to other patients, staff or documentation… Delivering care to patients with these behaviours could be exhausting and sometimes, particularly towards the end of a 'long day' (12 1/2 h shift), staff would ignore patients. P1338 | Staff working outside of ward routine to meet individual needs.<br><br>Constraints to addressing patient needs when unable to find out the cause, conflicting demands on staff time, and staff fatigue. |
| Gonski (2012) [66] | Staff members stated that they were sufficiently trained and a majority (n = 11) were able to confidently manage the behavioral problems. The respondents reported that they were able to build therapeutic relationships with both the patients and the carers and were also happy to provide help for both parties. In terms of communication, the nurses were very confident they could communicate with the patients, and therefore were able to interpret individual's needs. P62 | Training supports staff confidence to work with people living with dementia who have behaviours that challenge. Staff ability to communicate well with patients helps them build relationships with patients and understand their needs. |
| Luxford (2015) [67] | Early in the implementation period, a few clinicians reported difficulty in translating the carers' tips into a workable strategy for the hospital environment as they lacked confidence to write strategies based on 'non-clinical' tips. This issue was addressed through further training and the development of lanyards for clinicians to use which demonstrated how to write an effective TOP 5. P5<br><br>After implementing TOP 5, the majority of clinicians reported agreeing or strongly agreeing that TOP 5 was easy to use (91%), not time consuming (70%), decreased patient agitation and distress (74%), resulted in decrease use of restraint—physical or chemical (61%)—and made it easier to relate to carers (89%). P5 | Use of biographical tool supported by champions, training, and examples of how to implement information into care plan.<br><br>Use of biographical tool perceived to reduce patient agitation and distress and the use of restraints. |

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| Nichols (2002) [53] | "We built an interdisciplinary team that looks at the patient and the caregiver as a unit, works with them, and responds to the patient's behaviour as meaningful behaviour that needs to be understood. We understand that dementia patients have special needs. Using a team approach has allowed us to meet those needs in an acute care hospital." p186 | Working with carer to understand patient's needs. Understanding that behaviour is a communication of an unmet need. |
| Scerri (2015) [55] | Care worker (S32): I was thinking about this particular patient who did not need physiotherapy because he was here for respite care. He used to turn to all the staff to ask questions .. So every time I used to engage in a conversation with him and try to first calm him and reassure him because he was panicking and living in a situation as if it is real for him. P6 | Recognising patient needs and addressing them to reassure. Understanding from patient perspective. |
| Schneider (2010) [61] | We found that HCAs continuously ensured that patients were as comfortable as possible, some going out of their way to achieve this. One worker was even known to have sewed and adapted patients' clothing to maximise their comfort (and staff convenience, because this prevented frequent changes of clothing). Efforts were made to overcome language barriers between staff and non-English speaking patients and, when patients were distressed, HCAs often comforted them with actions as well as words: The male patient who becomes very distressed and cries was comforted greatly by H/CO who warmly cuddled up next to him, whilst on his observation, putting her arm around him and letting him snuggle into her, putting his head on her chest. (Fieldnote, Ward C) p28<br><br>We concentrate more, as you get to know the patients, the more you know their ways, you know their habits and if they've got a bad tummy and things like that and you get to know them; the job comes easier when you get to know them. It doesn't stop you getting hit sometimes, but you're aware of, you just get to know them and understand them a bit more. P47<br><br>"Invoking their practical autonomy, the HCAs also made minor adaptations within routines to suit individual patients. For example, medications were administered to all | Recognising and addressing patient needs to improve comfort for patients and benefit staff workload.<br><br>Importance of getting to know patients and benefits to workload.<br><br>Personalising tasks for needs of patients. |

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| | patients at approximately the same times every day on each ward, rather than being doled out individually; this ensured that every patient received his or her medication, as well as conserving staff time. However, within this routine, HCAs who were 'running' the medications would often make small concessions, for example by taking extra time to gain the trust of individual patients." P 49 | |
| Spencer (2013) [52] | Carers of patients with MMHU described staff as being 'well prepared' for dealing with confused patients, displaying patience and compassion. Respondents noted that patients who liked to wander were guided by staff when walking up and down rather than constantly being returned to their bed space, a behaviour observed by carers on standard care wards. P3<br><br>"Participants felt that staff had little understanding and limited training in dementia care, which carers felt resulted in patients being ignored, shouted at or threatened when staff were faced with uncooperative or challenging situations." P3 | Staff who have understanding of dementia and dementia care can meet the needs of patients.<br><br>Where staff lack understanding of behaviours that challenge they misinterpret them and attribute the problem to the patient, leading to poor care. |
| Waller (2015) [49] | Many of the environmental changes appear to have occurred as a consequence of the training that teams received before they started planning their projects. For example changes in staff attitudes such as investing in table cloths, laying tables, and purchasing coloured crockery, as well as increases in activities for patients such as the provision of newspapers or implementation of therapy hours, were reported; in the words of one team member, it is 'not just about the colour of the paint'. P64<br><br>Making spaces seem smaller and more familiar, and reducing the numbers of decisions that have to be made by patients in finding their way to places such as the toilet, the dining room or their own bed space, seems to significantly reduce agitation. P65 | Staff training helps staff recognise the needs of people living with dementia and make adaptions.<br><br>Changes that recognise the difficulties of people living with dementia will help reduce distress. |
| White (2016) [12] | Patients with any form of BPSD during their admission were five times more likely to have an antipsychotic prescribed during the admission (OR 4.99, 95% CI 1.15, 21.70, p=0.032). Antipsychotic prescription was five times more likely in people who | Behaviours that challenge increase likelihood of antipsychotic prescription. |

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| | experienced hallucinations (OR 5.04, 95% CI 2.10, 12.06, p≤0.001) or activity disturbances (OR 5.71, 95% CI 2.22, 14.70, p≤0.001) and seven times more likely with aggressive behaviours (OR 7.70, 95% CI 2.25, 26.31, p=0.001). Patients were three times more likely to have an antipsychotic prescribed when they experienced sleep disturbance (OR 3.35, 95% CI 1.45, 7.79, p=0.005).<br><br>In total, 55% of participants received non-pharmacological management during their admission. The most commonly used techniques were psychosocial interventions (36%) and staffing (17%) (Table 2). We found no evidence in the nursing or medical notes of ongoing monitoring or review of the effectiveness of these non-pharmacological interventions, or of a systematic way of using these techniques. | Lack of monitor of non-pharmacological management of behaviours that challenge so difficult to know effectiveness. |
| Williams (2011) [39] | We are testing a REACH education programme for domestic assistants and housekeepers… They had not considered the positive impact they could have in contributing to care and, without exception, were delighted to support the initiative. P15<br><br>REACH helps all staff to understand the cognitive difficulties experienced by people with dementia. It enables them to contribute in their role and promotes pride in the part they play in care. p15<br><br>Carers feel relieved that their loved one's condition is recognised and that hospital staff know how to respond to them, while the carers' sheet allows families to pass on crucial information and tips that will keep patients safe and improve their care'. P17 | Understanding the problem, knowing how can make a difference to patient experience and being able to take pride in work.<br><br>Working with carers to get to know the patient and know strategies that work well to improve patient safety. |

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Supplementary file 5: Characteristics of included papers

| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Baillie, 2015 [59] | UK | Published report | Evaluation of Barbara's Story | Qualitative | Written responses and focus groups | Patient satisfaction, patient safety |
| Baldwin, 2004 [48] | UK | Published paper | RCT of mental health liaison team | Quantitative | Validated tools | Depression, cognitive impairment, referrals |
| Banks, 2014 [40] | UK | Published paper | Evaluation of dementia champion training programme | Evaluation | Questionnaires of trainee knowledge and confidence in dementia, qualitative analysis of trainee reports | Impact of intervention on PLWD |
| Bray, 2015 [62] | UK | Published paper | The use of bay nursing and activity with PLWD in hospital | Description of the use of bay nursing and activities co-ordinators | Dementia care mapping, Patient experience questionnaires | Patient satisfaction |
| Brooker, 2014 [63] | UK | Published report | Evaluation of Royal College of Nursing development training programme | Evaluation report | Online survey, site evaluation (including locally determined methods such as dementia care mapping, | Patient satisfaction, carer engagement, reduced distress |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | incident reporting and patient satisfaction survey) | |
| Dowding, 2016 [60] | UK | Published paper | Development of pain management tool for PLWD in hospitals | Ethnographic study | Interviews, non-participant observation, medical notes review, documentary analysis | The identification and management of pain |
| Duffin, 2013 [64] | UK | Published paper | Description of interventions to improve care for PLWD in hospitals | Discussion paper | n/a | Patient satisfaction, patient safety |
| Edvardsson, 2012 [65] | Sweden | Published paper | Understanding the psychosocial climate of a ward | Qualitative | Observation | Patient satisfaction |
| Elliot, 2011 [45] | UK | Published paper | Description of role of Dementia Nurse Specialist | Discussion paper | n/a | Patient experience, patient safety, needs assessments, patient involvement in decision-making |
| Ellison, 2014 [42] | UK | Published report | Evaluation of Dementia Champions and | Evaluation | Interviews, staff survey | Patient experience, assessment of |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | Dementia Nurse Consultants | | | needs, reduced distress, reduced behaviours that challenge |
| Enns, 2014 [71] | Canada | Published paper | Quality improvement trial to reduce the use of physical restraints in hospital | Step wedged trial | Medical notes review | Use of restraints |
| Galvin, 2010 [10] | USA | Published paper | Evaluation of dementia awareness training programme | Pre-, post-, and delayed post test | Questionnaires of staff knowledge and confidence in dementia, interviews with trainees | Patient experience, |
| Goldberg, 2014 [50] | UK | Published paper | Patient experience and care on a Medical and Mental Health Unit compared with care on general wards | Qualitative findings from RCT | Non-participant observation (structured (dementia care mapping) and unstructured) | Patient experience, reduced distress, reduced behaviours that challenge, supporting patient choice (walking about the ward, food outside of mealtimes) |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Goldberg, 2013 [51] | UK | Published paper | Patient outcomes on a Medical and Mental Health Unit compared with general wards | Quantitative findings from RCT | Interviews, medical notes review, used of validated tools, non-participant observation (dementia care mapping) | Days spent at home, health status outcomes, behavioural and psychological symptoms, physical disability, cognitive impairment, carer strain, carer psychological wellbeing, carer satisfaction, patient mood and engagement |
| Gonski, 2012 [66] | Australia | Published paper | Outcomes of PLWD treated on a behavioural unit in a hospital | Retrospective review of medical records | Medical notes review, interviews with staff and carers | Carer satisfaction, Patient health care outcomes, behaviours that challenge, mediation, falls |
| Harwood, 2010 [72] | UK | Unpublished report | Development of Medical and Mental Health Unit | Discussion paper | n/a | Patient experience, patient orientation to |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | | time, supporting patient abilities, patient safety, supporting patient choice (walking about the ward), patient referrals, behaviours that challenge, medication review, carer satisfaction, carer involvement |
| Luxford, 2015 [67] | Australia | Published Paper | Clinician-carer communication tool | Survey | Survey with staff and carers | Acceptability and perceived benefits for patients |
| Moyles, 2011 [68] | Australia | Published paper | Best practice, the use of 'specials' | Qualitative Interviews | Interviews with staff | Patient experience |
| Nichols, 2002 [53] | USA | Published paper | The development of a specialist dementia care unit | Discussion paper | n/a | Improved communication with carers, improved patient experience |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Rosler, 2012 [69] | Germany | Published paper | Treatment of PLWD with hip fractures on specialist ward compared with general ward | Matched pair analysis | Validated scales | Functional status, use of antipsychotic medication, length of stay |
| Scerri, 2015 [55] | Malta | Published paper | Person centred care in hospital wards | Appreciative Inquiry / Qualitative interviews | Interviews | Family carer satisfaction, patient experience |
| Schneider, 2010 [61] | UK | Published report | The role of health care assistants in caring for people living with dementia | Ethnographic study | Participant observations, Interviews | Patient experience |
| Spencer, 2013 [52] | UK | Published paper | Family carer perceptions of care on Medical and Mental Health Unit compared with general wards | Qualitative findings | Interviews with family carers | Carer satisfaction, carer perception of care |
| Upton, 2012 [70] | UK | Published report | Multi-component bundle of evidence-based interventions | Qualitative and quantitative findings | Interviews, survey, medical records | Ward moves, infections, weight, catheter use, falls, mobility, place of discharge, use of antipsychotics, patient and carer satisfaction |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| Waller, 2015 [15] | UK | Published paper | Dementia friendly environmental adaptions in healthcare settings | Summary of findings of evaluations | Pre and post audit and locally determined data collection (observations, incident forms and falls data, medication review, interviews) | Behaviour that challenges, falls, patient engagement in activity, reduced agitation and distress, reduced use of antipsychotics |
| White, 2016 [12] | UK | Published paper | Management of behavioural and psychological symptoms of dementia in hospitals | Longitudinal cohort study | BEHAVE-AD scale<br>Non-participant Observation<br>Medical notes review | Behaviours that challenge and the use of pharmacological and non-pharmacological interventions for behavioural management |
| Williams, 2011 [39] | UK | Published paper | Development of the Butterfly Scheme | Discussion paper | Staff self-report for use of the scheme | Patient experience, identification and interpretation of behaviours that indicate a need (managing pain and continence), |

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| Reference | Country | Type of item | Focus | Method of study or type of paper | Data collection | Patient and /or carer outcomes |
|---|---|---|---|---|---|---|
| | | | | | | reducing patient distress, patient safety, carer satisfaction |
| Zieschang, 2010 [54] | Germany | Published paper | Feasibility study of dementia care specialist unit | Feasibility study | Staff survey, validated tools | Patient function, patient mobility, behaviours that challenge, length of stay, falls, use of restraints, use of antipsychotics |

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Supplementary file 6: Sample evidence from papers supporting CMOCs

| CMOC | Supporting evidence | Additional considerations or caveat evidence |
|---|---|---|
| CMOC 1: Understanding behaviour as communication to improve staffs' ability to respond | Banks (2014) [40]<br>One participant reported that use of the This is Me document had reduced the levels of medication prescribed and in turn the number of falls:<br>By having this document we have reduced the amount of medication the patient receives in hospital. Staff are much more likely to look into why the patient is behaving this way rather than get them prescribed medication. This in turn has reduced the number of falls during the day, therefore reducing the number of fractures and increased stays in hospital. (p727)<br><br>Galvin (2010) [10]<br>Participants were asked to rate their level of confidence in dealing with the hospitalized patient with dementia before and after the program. Participants reported a significant improvement in their overall confidence (Table | Spencer (2013) [52]<br>Standard care respondents felt that some staff displayed a negative attitude towards confused patients. Participants felt that staff had little understanding and limited training in dementia care, which carers felt resulted in patients being ignored, shouted at or threatened when staff were faced with uncooperative or challenging situations. In some cases, this led to a confrontation between nurses and family carers who reacted to what they perceived as unacceptable staff attitudes towards patients. These carers further highlighted that they had not formally reported for fear of repercussions towards their relatives:<br>She [health care assistant] kept shouting at him, turn over, turn over I can't get to you. So eventually I opened the curtains and said that man's confused he can't understand you. She [health care assistant] knew I was sitting |

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| | 2) as well as in each individual variable: assessment and recognition of dementia, managing dementia care, differentiating dementia from delirium, communicating with the patient and family and discharge planning. (p5)<br><br>Williams (2011) [39]<br>The carer's sheet asks about people's life history which can help staff talk to patients in a meaningful way, or distract or calm those who might be agitated. One woman had been a dance teacher so when she became agitated the nurses could talk about this or look at old photographs with her which helped to distract her. Another woman sometimes hit and kicked staff, but her son was able to tell us that this meant she was in pain, so again, we could respond accordingly. (p17) | outside the curtain and it didn't deter her, she was really shouting. (Wife of 69-year-old, male, standard care patient.) (p3)<br><br>Goldberg (2014) [50]<br>However, the psychological needs of the patients on the Unit were high and a minority of patients would call out persistently for long periods of time. Staff would try to comfort or distract them…. But the calling out would resume once the staff member left the patient and the conflicting demands on time meant staff would sometimes ignore their cries and attend to other patients, staff or documentation…. Delivering care to patients with these behaviours could be exhausting and sometimes, particularly towards the end of a 'long day' (12 1/2 h shift), staff would ignore patients. (p1338) |

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| CMOC 2: The role of experiential learning and creating empathy to encourage reflection for responsibilities of care | Baillie (2015) [59]<br>Barbara's Story engaged staff emotionally and prompted empathetic responses. They related to her as an individual and her experience. Staff related to Barbara as someone who could be their family member and for some staff, Barbara's experience mirrored their own family experiences. Staff expressed increased awareness of dementia and how it could be recognised, both within the Trust and outside. … Staff discussed how their own interactions with patients and behaviour had changed since watching Barbara's Story, and they often referred to changes they had observed in other staff too. Changes included:<br>giving more time to patients, improved communication, giving more information, and assisting patients who are looking lost. Staff also discussed how Barbara's Story had highlighted their professional responsibilities. (p28) | Baillie (2015) [59]<br>Time was a key constraint identified, along with the perception that 'people with dementia require a lot of your time' (Nurses8)…. Staff discussed the importance of having sufficient and high quality time for people with dementia (Nurses7, Nurses8) and the acknowledgement that time spent is of value:<br>Recognising that if you're spending one to one time with a person with dementia, whether it's walking around talking about where the boat goes from, that is valid. That's not, not doing work. (Nurses2) (p56)<br><br>Staff discussed how they put the Trust values into action. The value 'Patients first' had a strong resonance and there were many examples of going 'the extra mile' to benefit patients. Staff also discussed a perceived culture change within the Trust so that they felt able to spend longer with a patient or to challenge others about their practice. There |

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| | Duffin (2013) [64]<br>In one training session nurses, doctors and other staff wear specially designed goggles that restrict their vision, and put on a jacket which has small splints inserted in the arms to restrict movement of their upper body . This is to help staff understand the physical constraints faced by some older people. Darlene Romero, a matron across the trust's three older people's wards, who delivers the training, says: 'It's a real eye opener, and makes you realise how difficult it can be to go to the toilet.' (p16)<br><br>Williams (2010) [39]<br>REACH helps all staff to understand the cognitive difficulties experienced by people with dementia. It enables them to contribute in their role and promotes pride in the part they play in care. (p15) | was reference to standard setting and a new 'norm' having been established in the Trust. (p34)<br><br>Scerri (2015) [55]<br>Although family members appreciated that care is provided in time and when required, hospital staff felt that positive experiences with dementia patients can be achieved if they went the 'extra mile'; when they adopted initiatives or carried out actions that were not part of the normal care routine or that fall within their job description. (p6) |

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| CMOC 3: Clinical experts who legitimise priorities for care | Baldwin (2004) [48]<br>Liaison support comprised encouragement of person-centred care, education about mental disorder, nutrition and safety issues, and sign-posting to relevant services. Interventions were tailored to the patient and lasted for a maximum of 6 weeks. (p473)<br><br>Elliot (2011) [45]<br>As many ward doctors and nurses do not have adequate knowledge to address the needs of older patients who present with behaviour that challenges, part of the input from the DNS has focused on addressing this requirement, and this activity has assisted in reducing length of stay by discouraging inappropriate sedation, which generally contributes to poor patient outcomes. (p649)<br><br>Baillie (2015) [59]<br>Staff recognised that Barbara's Story had been developed within the context of the Trust | Goldberg (2014) [50]<br>Lisa walks down the walkway. The staff say ''Morning Lisa'' ''Morning'' as they walk past. . . Lisa says that this is a strange hospital. The auxiliary says ''If you want to go down that way with [the mental health nurse], she's lovely''. Lisa says ''You're all lovely''. The mental health nurse then talks to Lisa for some time. MMHU55. (p1339)<br><br>Ellison (2014) [42]<br>While Champions with different levels of seniority generally feel able to influence colleagues to some extent, challenging inappropriate attitudes and behaviour, implementing and embedding change within their own or other ward settings, and with other professional groups tends to be easier the more senior their position… "It's easier to address change with nurses if you're their manager" [SCN Champion - interviewee] (p34) |

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| | values and they discussed how they applied the values in action. There was recognition that each individual was representing the Trust and a sense of pride which prompted certain behaviours. There was also discussion about a culture change having taken place following on from Barbara's Story. Dementia was now seen as 'everybody's business' with a Trust-wide awareness. Staff discussed that Barbara's Story established standards expected within the Trust for patients generally and the expectation of improvement. It was also considered that Barbara's Story had established the role that all staff were expected to play in improving patients' experience, particularly for those who are most vulnerable. Barbara's Story had also set out an expectation for staff to be proactive about challenging care. (p60) | Nichols (2002) [53]<br>This change affected staff's job descriptions, the nature of their work, and what was considered important and not important… we did ask every member of the team… to sit down and think through how their jobs would be different if, in fact, they were responding to the needs of both the caregiver and the patient." (p187) |
| CMOC 4: Staff with confidence to adapt working practices and routines to individualise care | Edvardsson (2012) [65]<br>Sharing place and moment was characterised by staff actions such as: involving patients in | Rosler (2012) [69]<br>The CGU has additional components compared to conventional geriatric treatment: hidden exit |

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| | meaningful ways in tasks that had to be done; socially dining with patients; small talking with them in the day room; jointly performing different non-medicalised activities; or in other ways going beyond routines to make the content of the day mean a little extra for patients. The baseline activities at the ward consisted mostly of routine based medical tasks and the category sharing place and moment was observed when staff initiated different forms of leisure activities involving the patients. (p4)<br><br>Bray (2015) [62]<br>Bay nursing is a really positive move. I enjoy being more person focused, knowing what I am doing as a result of getting to know my patients better. Showers and baths can be offered more frequently and patients can have the time to do things more independently – that is, patients assisted to walk to the toilet as opposed to | doors, increased light in hallways and patient rooms, night lights, a treatment room on the wad to decrease patient transferral, a living and eating room, and a loop track for wandering patients. The number of beds was decreased from 28 (non-CGU ward) to 23 on the CGU. (p400)<br><br>Bray (2015) [62]<br>Bay nursing identifies one nurse as responsible for monitoring each bay for an entire shift, generally from 7.15am to 7.45pm, alongside a healthcare assistant. These two staff members have a maximum of seven patients under their care at any time. To achieve this, the 27-bed ward had two beds removed, one from a male bay and one from a female bay. The extra space was put to good use by introducing a communal table into each bay. (p22) |

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| | given a commode because of time pressures.' (p24)<br><br>Schneider (2010) [61]<br>Invoking their practical autonomy, the HCAs also made minor adaptations within routines to suit individual patients. For example, medications were administered to all patients at approximately the same times every day on each ward, rather than being doled out individually; this ensured that every patient received his or her medication, as well as conserving staff time. However, within this routine, HCAs who were 'running' the medications would often make small concessions, for example by taking extra time to gain the trust of individual patients. [p50}<br><br>Rosler (2012) [69]<br>In the CGU described here, physiotherapists and nurses tried to activate patients more individually by catching the right moment | |

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| | rather than working according to strict time schedules. However we cannot pin down the effect of a multidimensional intervention to a single factor. (p401) | |
| CMOC 5: Staff with responsibility to focus on psychosocial needs | Harwood (2010) [72]<br>The Occupational Therapist introduced occupational profiling using the Pool Activity Level instrument which was consistent with a person-centred care approach. This aims to identify the level of function for a patient on admission, and the development of care plans for personal care and other activities. As a result staff could engage patients in activities at a level where they could be successful, helping patients avoid the distressing experience of repeated failure. A health care assistant took specific responsibility for developing a programme of activities matched to ability using the occupational profile levels. She made contact with activities co-ordinators in the Mental Health Trust and kept a log of what she | Harwood (2010) [72]<br>What didn't work:<br>Activities co-ordinator not on duty every day; activities otherwise dependent on ward staffing levels. (p23)<br><br>Goldberg (2014) [50]<br>The staffing resources needed to keep patients safe could result in less time being available for other patients on the ward…. At times, activities coordinators and mental health nurses were allocated to watch the cohort bay, preventing their engagement in the organised activities and mental health assessments they were employed to provide. (p1338)<br><br>Bray (2015) [62] |

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| | had done. This included games (bowling, giant noughts and crosses, dominoes, ludo), quizzes, drawing and crafts, music, reminiscence, and exploration of senses. (p21)<br><br>Edvardsson (2012) [65]<br>The staff member involved all of the five patients in the day room in the activity, by talking to them interchangeably – each in a personalised way, asking for advice, comments and suggestions. It was a moment when she created a homely atmosphere through seeing, communicating and involving all persons present in the room at the same time. All of the patients present in the room expressed appreciation, interest and joy. (Field note no. 19, Friday 14.15, Day room) (p4)<br><br>Zieschang (2010) [54]<br>Daytime activities are conducted especially during the afternoon when staffing by the | Unfortunately, the ward has faced challenges because some of its staff have been moved to support other areas of the hospital, making it impossible to implement bay nursing at times because of inadequate staffing levels. This has been disheartening for staff that are unable to fulfil their new role, which they know has been effective. (p24)<br><br>Moyles (2011) [68]<br>The allocation of the special is ideally determined by the needs of the patient, yet in reality the allocation is more often determined by other constraints such as nurse shortages and budget constraints. However, it was clear that whatever the background of the special they generally did not have sufficient skills in how to care for a person with dementia. A MD expressed this as:<br>So they tend to call for a special, who will be someone who is extra, called in. Not necessarily a group of people who have experience in |

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| | nurses is reduced and the sun-downing phenomenon might occur. (p144) | aged care…it tends to be the most junior nursing staff with the least amount of education. (MD, P11) (p424) |
| CMOC 6: Building staff confidence to provide person-centred risk management | Zieschang (2010) [54]<br>Concern arose about promoting ambulation in a unit where patients are allowed to walk unassisted and where rejection of physical restraints might increase the number of falls and fall-related injuries especially fractures… Even though these events may happen, it is our estimation that the benefits of unrestricted ambulation outweigh the risks. Fall prevention interventions, such as review of medication, restrictive use of sedatives, adequate footwear and lighting are applied. (p143)<br><br>Nichols (2002) [53]<br>They [staff] observe that on this floor when patients in beds 6 through 21 get agitated, they can order restraints. But if patients in beds 22 through 30 become agitated, they are | Zieschang (2010) [54]<br>We promoted mobility on the unit among older and often frail patients with limited insight concerning their fall risk, the number of falls, especially injurious falls, appears to be an in important criterion to assess whether this concept of letting them wander at liberty is acceptable. (p141)<br><br>Bray (2015) [62]<br>The main challenge encountered when bay nursing was introduced was staff not understanding or appreciating that the bay could not be left unattended. It was reinforced to staff that if they left the bay the link with patients was lost and there was no one available to monitor patient safety or provide |

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| | supposed to go see the patient and find out why he or she is upset. (p186)<br><br>Luxford (2015) [67]<br>Surveys about the implementation process identified that the simplicity of theTOP5 process and strategies was considered by clinicians as the 'key to success'. Successful uptake relied on acceptability to staff and an existing culture of engagement with carers. Early in the implementation period, a few clinicians reported difficulty in translating the carers' tips into a workable strategy for the hospital environment as they lacked confidence to write strategies based on 'non-clinical' tips. This issue was addressed through further training and the development of lanyards for clinicians to use which demonstrated how to write an effective TOP 5. (p5) | assistance as required. Staff had therefore to ensure that appropriate cover was in place if they needed to leave the bay for any reason. As two members of staff are allocated to each bay, this was thought not to be overly restrictive, although it can become more challenging during longer shifts. (p23)<br><br>Galvin (2010) [10]<br>Hospital A instituted a "Code Green" procedure that placed patients at risk for elopement in green gowns and trained staff on appropriate dementia-friendly responses and precautions. (p10) |

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